

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS  
BOSTON DIVISION**

Musket Research Associates, Inc.,

Plaintiff,

v.

Ovion, Inc.,  
William S. Tremulis, and  
Jeffrey P. Callister,

Defendants.

**Case No. 05-10416 MEL**

Ovion, Inc.,

Counterclaimant,

v.

Musket Research Associates, Inc.,  
David B. Musket, and  
Sue Ann Latterman,

Counterdefendants.

**DEFENDANTS' OPPOSITION AND MEMORANDUM IN OPPOSITION  
TO MRA'S MOTION FOR ENTRY OF A SINGLE-TIER PROTECTIVE ORDER**

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**DEFENDANTS' OPPOSITION TO MRA'S MOTION  
FOR ENTRY OF A SINGLE-TIER PROTECTIVE ORDER**

Defendants hereby oppose Plaintiff's motion for a single-tier protective order that does not provide for Outside Counsel Eyes Only ("OCEO") designations. Defendants have attached Defendants' Proposed Protective Order as Exhibit 1 hereto. For the reasons set forth below, Defendants respectfully request that the Court enter their proposed protective order for purposes of discovery in this matter.

Pursuant to Local Rule 7.1(d), Defendants request an oral argument on the matters raised by Plaintiff's motion and Defendants' opposition.

**DEFENDANTS' MEMORANDUM IN OPPOSITION TO  
MRA'S MOTION FOR ENTRY OF A SINGLE-TIER PROTECTIVE ORDER**

**I. INTRODUCTION**

The core issue raised by Plaintiff's motion is whether the Court should enter a protective order providing that the parties may designate certain types of highly confidential information as Outside Counsel Eyes Only.

As Plaintiff concedes in its moving papers, Plaintiff previously agreed that the parties could designate information as Outside Counsel Eyes Only. (MRA Memo at 2 ("MRA and Ovion agreed to treat information they exchanged in the litigation as attorneys' eyes only pending the Court's entry of an appropriate protective order.").) In reliance on that understanding, Defendants have produced a great deal of highly confidential information relating to Defendant Ovion, Inc.'s efforts to find potential investors and business partners, including highly confidential information relating to due diligence by potential investors and business partners. In addition, Defendants have produced highly confidential information for which Defendants owe an obligation of confidentiality to other parties not involved in this litigation.

Furthermore, the confidential information at issue is quite current. Now, in a bait and switch, Plaintiff insists that it and its principals should have unfettered access to all this information.

Plaintiff concedes that the information in question qualifies to be treated as confidential under a protective order. (MRA Memo at 12 (“MRA’s proposed order will protect the confidentiality of the documents that Ovion has designated ‘Outside Counsel Eyes Only’ by considering them as ‘Confidential.’”).) The issue is whether, by filing a frivolous lawsuit, Plaintiff can obtain full access to Defendants’ confidential information.<sup>1</sup> (In this case, Plaintiff has brought unfounded claims in an effort to extort Defendants, as explained below.)

Plaintiff argues that the parties are not competitors and that Defendants therefore do not risk any injury from the disclosure of confidential information to Plaintiff and its principals. (MRA Mot. at 2.) To the contrary, Plaintiff holds itself out as a finder and an advisor to emerging healthcare companies looking for investors and business partners. Accordingly, Defendants’ prospective competitors all are clients or potential clients of Plaintiff. For these and other reasons, Defendants (and the third parties to which Defendants owe obligations of confidentiality) could suffer grave and irreparable harm if Plaintiff and its principals were granted access to Defendants’ confidential information.

For similar reasons, a two-tier protective order as Defendants propose, which provides for Outside Counsel Eyes Only designations, will increase efficiencies in this case. Many of the third parties with relevant information are located outside this jurisdiction. If the protective order in this case does not provide for Outside Counsel Eyes Only designations, then courts all

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<sup>1</sup> Out of more than 20,000 pages that Ovion has produced to date, Defendants have identified four (4) pages of correspondence between the parties that were inadvertently designated as Outside Counsel Eyes Only. (MRA Exhibit C.8.) Defendants agree that these documents should not be designated Outside Counsel Eyes Only. Otherwise, Defendants believe that the

over the nation will be met with motions for protective orders and motions to compel as subpoenas are served on third parties in this case.

In addition, Plaintiff alleges that Defendants improperly used Plaintiff's alleged "work product." Plaintiff apparently is unable, however, to identify its own alleged "work product" without access to Defendants' confidential information. (*See* Ovion Exhibit 5, MRA's Interrogatory Responses, at 4-5.) Plaintiff's position defies common sense. The Court should require Plaintiff to identify with particularity its alleged work product without access to Defendants' confidential information. Otherwise, Plaintiff will use Defendants' confidential information as a road map for identifying Plaintiff's alleged work product.

## **II. BACKGROUND**

### **A. The Parties**

In this action, the Defendants are Ovion, Inc. ("Ovion"), William S. Tremulis ("Mr. Tremulis"), and Jeffrey P. Callister ("Mr. Callister") (collectively the "Ovion Parties"). The Plaintiff is Musket Research Associates, Inc. ("MRA"). Ovion has counterclaimed against MRA, David B. Musket ("Mr. Musket"), and Sue Ann Latterman ("Ms. Latterman") (collectively the "MRA Parties").

Mr. Tremulis and Mr. Callister founded Ovion in 1996 as a start-up medical device company with a focus on minimally invasive alternatives to surgical sterilization. For the first several years, Mr. Tremulis and Mr. Callister primarily funded Ovion with their own resources and investments from "angel" investors. In 2002, Ovion was sued by Conceptus, Inc. ("Conceptus") seeking a declaratory judgment that Conceptus did not infringe Ovion's patent. In

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other documents, which were cited by Plaintiff in its moving papers, are properly designated as Outside Counsel Eyes Only.

settlement of that litigation in 2003, Ovion received \$4 million plus future royalties from Conceptus. These funds were used for Ovion's ongoing operations.

Mr. Musket is the president and founder of MRA. (MRA Memo at 2.) Ms. Latterman is its principal employee. (*Id.*) MRA allegedly operates as a finder/advisor for "emerging healthcare companies" looking for investors. (*See* Ovion Exhibit 3.) Ovion now understands that Mr. Musket also is a member and managing director for ProMed Partners, L.P., which is a "healthcare investment fund," and the president of DBM Corporate Consulting, Ltd. (*Id.*)

**B. Pursuant To A Written Engagement Letter, Ovion Retained MRA As A "Nonexclusive Finder/Advisor"**

In July, 2004, Ovion retained MRA "as a nonexclusive finder/advisor" on the terms set forth in a written agreement (the "Engagement Letter"). (*See* Ovion Exhibit 2.) The present dispute relates to this agreement. MRA essentially ignores the terms of the Engagement Letter in its description of the case, principally because its contentions contradict the express language of the parties' written agreement.

**1. Nothing In The Engagement Letter Limits Ovion's Use Of MRA's Work Product**

Contrary to MRA's contentions, nothing in the Engagement Letter limits how Ovion could use MRA's work product. As a nonexclusive finder/advisor, MRA agreed to provide the following services:

MRA shall (i) analyze the financial performance and projections of the Company and provide advice regarding the appropriate valuation range for the new equity capital; (ii) assist in the development of presentation materials for investor solicitations; (iii) contact qualified investors and, if acceptable to you or your representative, send the necessary documents ourselves or through your office . . . ; (iv) after appropriate screening, set up and accompany you to meetings with interested parties as often as scheduling allows; and (v) manage ongoing discussions and coordinate the closings with investors solicited, or caused to be solicited by MRA.

(Ovion Exhibit 2, Engagement Letter, ¶ 2(a).) Contrary to MRA's representations, the Engagement Letter specifically contemplates a merger and acquisition involving Ovion and a corporate partner. (*Id.*, ¶ 3(d).) MRA alleges that Ovion somehow misled MRA about the possibility of a merger and acquisition. Such allegations are frivolous in view of the express language of the Engagement Letter. (*Id.*)

**2. MRA Agreed That It Would Be Compensated For Its Services Only In The Event Of Certain Contingencies**

Regarding compensation, MRA agreed that it would be compensated for its services "as a nonexclusive finder/advisor" by payment of a "Finder's Fee," an "Advisory Fee," or a "Success Fee," but only under limited contingencies as set forth in the parties' written agreement. (Ovion Exhibit 2, Engagement Letter, ¶¶ 3(a), 3(c)-(d).) Outside of these limited contingencies, the parties' written agreement provided for no compensation to MRA, regardless of the services provided by MRA or how MRA's work product was used. (*Id.*, ¶ 3.)

**a. Contingent Compensation For MRA's Services As A "Nonexclusive Finder"**

Specifically, with respect to MRA's role as a nonexclusive "finder," MRA agreed that it would receive a "Finder's Fee" only in the event of the following contingencies:

- seven percent (7%) of the aggregate cash proceeds received by OVION from . . . "MRA Contacts"
- three percent (3%) of the aggregate cash proceeds received by OVION from . . . "OVION VC Contacts"
- two [percent] (2%) of the aggregate cash proceeds received by OIVON from . . . US Venture Partners.

(Ovion Exhibit 2, Engagement Letter, ¶ 3(a).) Indeed, the parties' agreement specifically provided: "MRA shall receive no fees for any entity that is not either an MRA Contact or an Ovion VC Contact." (*Id.*) Moreover, absent a countersignature from Ovion evidencing its



consent, MRA was precluded from adding potential investors to the list of “MRA Contacts.”  
(*Id.*)

Pursuant to the Engagement Letter, MRA also agreed that it would receive a “Success Fee” of no more than \$225,000 (minus any Finder’s Fees) only in the event of the following contingency:

If, during the term of this Agreement, OVION consummates a Placement other than a Placement involving a corporate partner, and the [Finder’s Fees] payable to MRA . . . are less than \$225,000 . . .

(Ovion Exhibit 1, Engagement Letter, ¶ 3(c).) The “Success Fee” provision expressly expired upon termination of the agreement. (*Id.*)

**b. Contingent Compensation For MRA’s Services As A “Nonexclusive Advisor”**

With respect to MRA’s role as a nonexclusive “advisor,” MRA agreed that it would receive an “Advisory Fee” of no more than \$225,000 (minus any Finder’s Fees) in the event of the following contingency:

If, during the term of this Agreement, OVION consummates a merger, acquisition or Placement involving a corporate partner . . . [before] the 180th day following the date [of the Engagement Letter].

(Ovion Exhibit 2, Engagement Letter, ¶ 3(d).) The “Advisory Fee” provision expressly expired on the earlier of (1) the 180th day following the date of the Engagement Letter or (2) termination of the Agreement. (*Id.*) Accordingly, as of either the 180th day or termination of the Agreement, MRA was no longer entitled to an Advisory Fee for any of its services in the event that Ovion consummated a merger or acquisition involving a corporate partner. (*Id.*, ¶¶ 3(d).)

In short, the parties agreed in writing that MRA would be compensated for its services as a “nonexclusive finder/advisor” only in the event of certain contingencies. Absent the realization

of those contingencies, MRA was not entitled to any compensation for its services, pursuant to the parties' written agreement.

**C. MRA's Performance Was Unsatisfactory, Untimely, And Adverse To Ovion's Interests**

In July, 2004, when Ovion engaged MRA as a "nonexclusive finder/advisor," Ovion already had prepared presentation materials and was talking with potential investors and business partners. Before the parties executed the Engagement Letter, MRA represented that it would devote substantial resources to this effort and that Ovion should expect positive results within a short time frame. MRA further acknowledged that time was of the essence.

Despite MRA's representations, it did not devote adequate resources to its role as a "finder" and an "advisor" for Ovion, particularly not in a timely fashion. In large measure, MRA relied on Ovion and others to perform the services that MRA had agreed to provide in exchange for contingent compensation. After more than six months, Ovion had received no offers from any of the "MRA Contacts." Indeed, the only offer that Ovion had received was an offer from US Venture Partners, a venture capital organization that Ovion had been talking to long before MRA became involved. MRA recommended that Ovion decline the offer from US Venture Partners.

Ovion is now aware that Mr. Musket is a member and the managing director of ProMed Partners, L.P., which holds itself out as a "healthcare investment fund." (See Ovion Exhibit 3.) On present information and belief, it appears that MRA and Mr. Musket, by delaying and deterring potential investors in Ovion, were attempting to position Ovion so that they and their other interests could invest in Ovion on terms favorable to them and unfavorable to Ovion. MRA, Mr. Musket, and Ms. Latterman were privy to Ovion's cash position and were well aware that, if MRA did not produce positive results in a timely fashion, Ovion's position would become

less and less tenable. On information and belief, MRA and Mr. Musket have employed this same tactic with other clients, acting contrary to the clients' interests while purporting to represent them.

**D. Ovion's Merger With And Acquisition By American Medical Systems**

On June 3, 2005, Ovion merged with and was acquired by American Medical Systems, Inc. ("AMS"). On February 16, 2005, Ovion had signed a letter of intent, agreeing to negotiate exclusively with AMS. Ovion promptly informed MRA that it had agreed to negotiate exclusively with a potential corporate partner. Ovion also terminated its agreement with MRA.

MRA, Mr. Musket, and Ms. Latterman admit that they, individually and collectively, did not do any of the following:

"communicate with AMS on behalf of Ovion"

"set up any meetings between AMS and Ovion"

"accompany Ovion or its representatives to any meeting with AMS or its representatives"

"manage any discussions between Ovion and AMS"

"coordinate the closing between Ovion and AMS"

(Ovion Exhibit 4, MRA Responses to Requests to Admit, at 2-3.)

**E. Pursuant To The Parties' Written Agreement, MRA Is Not Entitled To Any Compensation**

As discussed above, the parties' agreement provided that MRA would receive compensation for its services only if certain contingencies were realized. None of those contingencies were realized. Accordingly, pursuant to the express terms of the parties' written agreement, MRA is not entitled to any compensation. More specifically, because the pertinent contingencies were not realized, MRA is not entitled to a Finder's Fee, or a Success Fee, or an

Advisory Fee, which are the only forms of compensation contemplated by the parties' Engagement Letter.

**1. MRA Is Not Entitled To A "Finder's Fee"**

First, MRA is not entitled to a "Finder's Fee" because Ovion never received any "cash proceeds" from either an "MRA Contact" or an "Ovion VC Contact." AMS is neither an MRA Contact nor an Ovion VC Contact, as those terms were defined by the parties. The Engagement Letter between Ovion and MRA expressly provides: "MRA shall receive no fees for any entity that is not either an MRA Contact or an Ovion VC Contact." (Ovion Exhibit 2, Engagement Letter, ¶ 3(a).)

**2. MRA Is Not Entitled To A "Success Fee"**

Second, MRA is not entitled to a "Success Fee" because AMS is a corporation and MRA was entitled to a Success Fee only in the event of "a Placement other than a Placement involving a corporate partner." (Ovion Exhibit 2, Engagement Letter, ¶ 3(c) (emphasis added).) Moreover, MRA was entitled to a Success Fee only if such a non-corporate "Placement" was consummated "during the term of this Agreement," *i.e.*, the agreement set forth in the Engagement Letter. (*Id.*) As discussed above, the merger and acquisition among Ovion and AMS was not consummated until June, 2005, long after the agreement between Ovion and MRA was terminated in March, 2005.

**3. MRA Is Not Entitled To An "Advisory Fee"**

Third, MRA is not entitled to an "Advisory Fee" because (1) the merger and acquisition among Ovion and AMS was consummated more than 180 days after the date of the Engagement Letter and (2) after the agreement was terminated. As discussed above, the Engagement Letter expressly provided that the "Advisory Fee" provision expired 180 days after the date of the Engagement Letter. (Ovion Exhibit 2, Engagement Letter, ¶ 3(d).) The Engagement Letter was

dated in July, 2004. (*Id.* at 1.) The merger and acquisition among Ovion and AMS was consummated in June, 2005, more than 300 days after the date of the Engagement Letter. Moreover, the merger and acquisition was consummated after the agreement set forth in the Engagement Letter was terminated in March, 2005.

**F. MRA's Conduct Is Consistent With Its Pattern Of Extorting Its Clients**

As discussed above, MRA is not entitled to any compensation pursuant to the parties' written agreement as set forth in the Engagement Letter. Moreover, after MRA had been representing Ovion for more than six months as a "nonexclusive finder/advisor," Ovion had received only one offer, from a venture capital group with which Ovion had a preexisting relationship. MRA recommended that Ovion decline that offer. None of the "MRA Contacts" ever made an offer. It appears that MRA, acting in its own interests and against its client's interests, was setting up Ovion as an investment for Mr. Musket and his other interests on terms favorable to them and unfavorable to Ovion.

Nevertheless, although MRA was not entitled to any compensation, MRA began attempting to extort money from Ovion shortly after Ovion informed MRA that Ovion had executed a letter of intent with a potential corporate partner. Specifically, MRA began threatening to sue for compensation to which it is not entitled. This threat had at least three inherent aspects: (1) the expense, distraction, and uncertainty inherent in litigation; (2) the risk that highly confidential information would be publicly disclosed or disclosed to parties such as MRA during the course of litigation; and (3) the specter that litigation would disrupt the ongoing negotiations between Ovion and AMS.

On information and belief, MRA, Mr. Musket, and Ms. Latterman have used the same strategy to extort money from other clients. More specifically, after MRA has entered written agreements with its clients that limit MRA's compensation to certain contingencies, MRA

nevertheless has demanded compensation when those contingencies were not realized. To persuade clients to acquiesce to these unwarranted demands, MRA, Mr. Musket, and Ms. Latterman have threatened frivolous litigation based on unfounded claims. It appears that they are attempting to follow the same strategy here.

### **III. THE PROTECTIVE ORDER SHOULD ALLOW THE PARTIES TO DESIGNATE CERTAIN INFORMATION AS OUTSIDE COUNSEL EYES ONLY**

Both parties agree that the Court should enter a protective order to govern information furnished in discovery in this case. The fundamental issue raised by MRA's motion is whether the protective order should allow a party to designate information as "Outside Counsel Eyes Only." To gain access to Ovion's confidential information, MRA contends that the protective order should have no provision for Outside Counsel Eyes Only information. Given the business practices of MRA and its principals, Ovion would suffer grave and irreparable harm if MRA and its principals were to gain access to Ovion's confidential information.<sup>2</sup>

Much of the information produced by Ovion in this matter is highly confidential and, in many instances, governed by obligations of confidentiality to other non-parties. Most of this information is quite current. Indeed, MRA concedes that Ovion should be entitled to designate this information as Confidential under a protective order. (MRA Memo at 12 ("MRA's proposed order will protect the confidentiality of the documents that Ovion has designated 'Outside Counsel Eyes Only' by considering them as 'Confidential.'").) Thus, the core issue is whether MRA, Mr. Musket, and Ms. Latterman should be granted unfettered access to this information.

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<sup>2</sup> MRA argues that, because Ovion gave MRA access to some confidential information pursuant to a confidentiality agreement, MRA therefore should receive access to all of Ovion's confidential information. Such an argument is without merit. Moreover, at the time that Ovion gave MRA access to some confidential information, Ovion was not yet aware of MRA's disregard for contractual obligations generally and confidentiality obligations specifically.

As MRA admits in its moving papers, MRA previously agreed that the parties should be able to designate information as Outside Counsel Eyes Only in this litigation. (MRA Memo at 2 (“MRA and Ovion agreed to treat information they exchanged in the litigation as attorneys’ eyes only pending the Court’s entry of an appropriate protective order.”).) Now that Ovion has produced the information, MRA argues that MRA, Mr. Musket and Ms. Latterman should be given full access to the information. The Court should not countenance MRA’s bait and switch tactic.

**A. Contrary To MRA’s Representations, Two-Tier Protective Orders Are Common, Not Rare**

In its moving papers, MRA repeatedly asserts that protective orders rarely provide for OCEO designations. Contrary to MRA’s representations, protective orders frequently provide for OCEO designations, particularly for the types of information at issue here. *See, e.g.* 6 JAMES WM. MOORE, MOORE’S FEDERAL PRACTICE § 26.105[8][b] (3d ed. 2005)(“[T]he courts frequently order that disclosure be limited to counsel . . .”) (citing cases); *Biovail Corp. Int’l v. Hoechst Aktiengesellschaft*, No. 98-1434, 1999 U.S. Dist. LEXIS 21621, at \*5-6 (D.N.J. Nov. 12, 1999) (two-tier protective order: confidential or attorneys’ eyes only); *Ventrassist Pty, Ltd. v. Heartware, Inc.*, 377 F. Supp.2d 1278, 1289 (S.D. Fla. 2005) (same).

**B. Based On The Understanding That Information Could Be Designated As Outside Counsel Eyes Only, Ovion Has Produced Highly Confidential Information, Including Information For Which Ovion Owes An Obligation Of Confidentiality To Other Parties**

The subject matter of this lawsuit relates directly to Ovion’s efforts to find investors and business partners. In the course of such activities, Ovion has exchanged highly confidential information, pursuant to confidentiality and non-disclosure agreements, with prospective investors and business partners that were conducting due diligence as they evaluated Ovion. Not surprisingly, given the subject matter at issue, much of the information produced by Ovion in



this litigation is highly confidential. Indeed, in its moving papers, MRA admits that the documents that Ovion has designated as OCEO qualify as confidential information. (MRA Memo at 12 (“MRA’s proposed order will protect the confidentiality of the documents that Ovion has designated ‘Outside Counsel Eyes Only’ by considering them as ‘Confidential.’”)).) Moreover, as MRA admits, Ovion produced the information to MRA based on the understanding that it would be treated as OCEO. (MRA Memo at 2.)

In addition, in discovery to date, Ovion has produced information that it received from prospective investors and business partners. For much of this information, Ovion owes an obligation of confidentiality to the prospective investors and business partners which provided the information to Ovion. (*See, e.g.*, MRA Exhibit C.3 at OVN001544-46.) Under the guise of moving for a protective order, MRA is demanding that MRA, Mr. Musket, and Ms. Latterman receive full access to this third-party information. Such disclosures could put Ovion in the position of violating obligations of confidentiality to these third parties.

**C. Ovion Would Suffer Irreparable Injury If Its Highly Confidential Information Were Disclosed To MRA, Mr. Musket, Or Ms. Latterman**

Given the subject matter at issue, it is imperative that Ovion be able to designate highly confidential information as Outside Counsel Eyes Only in this litigation. MRA makes one principal argument to the contrary. Specifically, MRA argues that, because Ovion and MRA are not competitors, Ovion would suffer no harm if its highly confidential information were disclosed to MRA, Mr. Musket, and Ms. Latterman. MRA’s argument is based on a misleading half-truth.

MRA holds itself out as a finder and an advisor “focused on emerging healthcare companies.” (*See* Ovion Exhibit 3.) Ovion’s prospective competitors are just those types of companies. (*See* Ovion Exhibit 7 at 73-76.) In other words, Ovion’s prospective competitors are



exactly the type of companies that MRA solicits as clients. Accordingly, if MRA were to gain access to any more of Ovion's highly confidential information, then that information would be at risk of disclosure to Ovion's competitors. Moreover, much of the information in question is third-party information Ovion received from potential investors and business partners. All of these third parties operate in the healthcare arena. MRA should not have access to such information, including information that would reveal the negotiation strategies employed by these third parties.

In short, when arguing that MRA does not compete with Ovion, MRA ignores the fact that, as a finder and an advisor to the healthcare industry, MRA likely will do business with parties that should not have access to either Ovion's confidential information or the confidential information that Ovion received from third parties. In addition, as discussed above, Mr. Musket is involved in other companies, such as ProMed, operating in the same healthcare arena.

**D. MRA Has Demonstrated That It Cannot Be Trusted With Ovion's Confidential Information**

Furthermore, MRA has demonstrated that it cannot be trusted with Ovion's confidential information. For instance, after Ovion signed a letter of intent with AMS, Ovion informed MRA that Ovion had agreed to negotiate exclusively with a potential corporate partner for a possible merger and acquisition. That information was highly confidential at that time. Even though MRA had signed a confidentiality agreement barring MRA from disclosing Ovion's confidential information, MRA nevertheless publicly disclosed the fact that Ovion had been engaged in negotiations for a possible merger and acquisition, using this litigation as a vehicle for the disclosures. Moreover, in furtherance of its attempts to extort Ovion, MRA made these disclosures at a time and in a fashion that threatened to disrupt Ovion's negotiations with AMS.

**E. MRA Should Be Required To Identify Its Alleged Work Product Without Access To Ovion's Confidential Information**

MRA alleges that Ovion improperly used MRA's alleged "work product." MRA apparently is unable, however, to identify its own alleged "work product" without access to Ovion's confidential information. (*See* Ovion Exhibit 5, MRA's Interrogatory Responses, at 4-5.) MRA's position defies common sense. The Court should require MRA to identify with particularity its alleged work product without access to Ovion's confidential information. Otherwise, MRA will use Ovion's confidential information as a road map for identifying MRA's alleged work product.<sup>3</sup>

**F. A Two-Tier Protective Order Will Promote Efficiencies**

Moreover, a two-tier protective order as proposed by Ovion, which provides for Outside Counsel Eyes Only designations, will increase efficiencies in this case. Many of the third parties with relevant information are located outside this jurisdiction. If the protective order in this case does not provide for Outside Counsel Eyes Only designations, then courts all over the nation will be met with motions for protective orders and motions to compel as subpoenas are served on third parties in this case.

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<sup>3</sup> *See, e.g., Staffbridge, Inc. v. Gary D. Nelson Assoc.*, No. 02-4912, 2004 Mass. Super. LEXIS 215, at \*10 (Super. Ct. Mass. June 11, 2004) (attached as Ovion Exhibit 7) ("[Discovery] cannot be at the risk of the defendants' entitlement to know with precision what is claimed as a trade secret before any discovery of the defendants' allegedly infringing materials."); *AutoMed Techs., Inc. v. Eller*, 160 F. Supp.2d 915, 926 (N.D. Ill. 2001) ("[P]laintiff will normally be required first to identify with reasonable particularity the matter which it claims constitutes a trade secret, before it will be allowed (given a proper showing of need) to compel discovery of its adversary's trade secrets. . . . It is not enough to claim that defendants will be able to learn the details through discovery. Plaintiff must provide them now so we can evaluate the relevance of plaintiff's discovery and address any objections.").

**G. The Court Should Adopt Ovion's Proposed Protective Order**

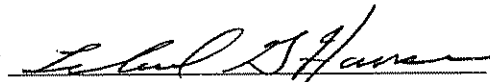
Ovion has attached a proposed protective order as Exhibit 1. Ovion's proposed protective order provides that parties producing information in this litigation may designate certain types of information as Outside Counsel Eyes Only. Ovion respectfully requests that the Court enter Ovion's proposed protective order for purposes of discovery in this litigation.

**IV. CONCLUSION**

For all the foregoing reasons, the Court should deny MRA's motion for a single-tier protective order. Instead, the Court should entered Ovion's proposed protective order (attached as Exhibit 1), which provides for Outside Counsel Eyes Only designations as appropriate in this case.

Respectfully submitted,

By



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*Jeffrey P. Callister and Counterclaimant*

*Ovion, Inc.*

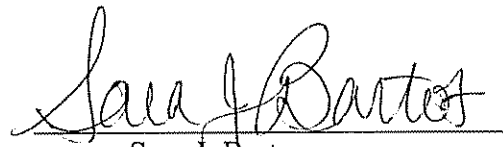
**Certificate of Service**

The undersigned hereby certifies that a copy of the foregoing document was served by email and mail to:

Arthur S. Beeman  
Pamela K. Fulmer  
DLA Piper Rudnick Gray Cary US LLP  
153 Townsend Street, Suite 800  
San Francisco, CA 94107  
arthur.beeman@dlapiper.com  
pam.fulmer@dlapiper.com

Brooks A. Ames  
DLA Piper Rudnick Gray Cary US LLP  
One International Place, 21st Floor  
100 Oliver Street  
Boston, MA 02110  
brooks.ames@dlapiper.com

this 7th day of December, 2005.

  
Sara J. Bartos

## **Ovion Exhibit 1**

IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS  
BOSTON DIVISION

Musket Research Associates, Inc.,

Plaintiff,

v.

Ovion, Inc.,  
William S. Tremulis, and  
Jeffrey P. Callister,

Defendants.

Case No. 05-10416 MEL

Ovion, Inc.,

Counterclaimant,

v.

Musket Research Associates, Inc.,  
David B. Musket, and  
Sue Ann Latterman,

Counterdefendants.

**DEFENDANTS' PROPOSED PROTECTIVE ORDER**

This Court, having considered the arguments and evidence raised in the context of Plaintiff Musket Research Associates, Inc.'s motion for a protective order, the memoranda in support of and opposition to, and the records on file, hereby ORDERS:

**(1) PROCEEDINGS AND FORM OF INFORMATION GOVERNED**

This Order shall govern any information furnished by any party or nonparty to any party in connection with this litigation. The form of information governed by this Order includes, but is not limited to, documents and things, responses to requests to produce documents or other things, privileged document logs, responses to interrogatories, responses to requests for admissions, deposition testimony and exhibits, and all copies, extracts, summaries, compilations, designations and portions thereof.

**(2) DEFINITION OF CONFIDENTIAL INFORMATION**

a. The term “Confidential Information” shall mean information that the designating party reasonably and in good faith believes constitutes information which if disclosed: (1) would reveal trade secrets, confidential or proprietary information, or technical or business advantages, (2) would violate a legal or contractual obligation of the designating party to protect from disclosure, or (3) would be invasive of an individual’s privacy interests.

b. The term “Confidential – Outside Counsel Eyes Only Information” shall mean information that the designating party reasonably and in good faith believes constitutes information which, if disclosed to persons described in section 6(d) below, (1) would reveal trade secrets, confidential or proprietary information, or technical or business advantages, (2) would violate a legal or contractual obligation of the designating party to protect from disclosure, or (3) would be invasive of an individual’s privacy interests. .

The scope of this Order shall be understood to encompass not only those items or things which are expressly designated as Confidential Information or Confidential – Outside Counsel Eyes Only Information, but also any information derived therefrom, and all copies, excerpts, and summaries thereof, as well as testimony and oral conversation derived therefrom.

**(3) DESIGNATION OF CONFIDENTIAL INFORMATION**

a. Any information produced in this litigation that is reasonably believed by the producing party to contain Confidential Information shall be designated as “CONFIDENTIAL” and any information produced in this litigation that is reasonably believed by the producing party to contain Confidential – Outside Counsel Eyes Only Information shall be designated as “OUTSIDE COUNSEL EYES ONLY”.

b. The designation of Confidential Information or Confidential – Outside Counsel Eyes Only Information shall be made at the following time:

(1) For documents and things, at the time of the production of the documents or things;

(2) For written responses to interrogatories or requests for admissions, at the

time of the written response;

(3) For declarations, pleadings, and exhibits thereto, at the time of the filing or use of such declaration, pleading or exhibit;

(4) For deposition testimony, at the time of the testimony (see section 8 (b)) or within twenty (20) days after receipt by the designating party of the transcript of the deposition;

(5) For disclosures at a hearing or trial, at the time of such hearing or trial; and

(6) For oral disclosures (other than deposition, hearing or trial testimony), at the time of such oral disclosure and through confirmation in writing within twenty (20) days of the disclosure thereof.

c. The designation of Confidential Information or Confidential – Attorney Eyes Only Information shall be made in the following manner:

(1) For documents and exhibits, by placing a legend on at least the first page and each page on which affected information appears;

(2) For tangible objects, by placing a label or tag on the object or the container therefor, or if not practicable, as otherwise agreed, in writing;

(3) For written responses to interrogatories or requests for admissions, in writing on at least the cover page of any such responses and separately within each such response;

(4) For declarations and pleadings, in writing on the cover page sheet of any such declaration or pleading;

(5) For depositions, by making a statement on the record at the time of the deposition, or in writing within twenty (20) days after receipt by the designating party of the transcript of the deposition;

(6) For hearings and trial, by making a statement on the record; and

(7) For any other oral disclosures, by making a statement at the time of the disclosure and through confirmation in writing within twenty (20) days of the disclosure.

d. It shall be the duty of the party seeking protection of Confidential Information or



Confidential – Outside Counsel Eyes Only Information to indicate to the other party or its attorney of record which of the materials and testimony are considered Confidential Information or Confidential – Outside Counsel Eyes Only Information. Designations shall be made with as much specificity as reasonably possible.

e. Each party retains the right to subsequently re-designate information it has produced in this litigation and to require such information to be treated in accord with such designations from that time forward. Upon re-designation of any information to a higher level of confidentiality, the receiving party shall take reasonable efforts to secure the return of the re-designated information from unqualified persons as described in paragraph 6, and if data or information has been extracted or copied from the re-designated information by an unqualified person, that information or data shall be expunged and not be used by the unqualified person.

f. If it comes to a party's attention that information it designated for protection does not qualify for protection at all, or does not qualify for the level of protection initially asserted, that party must promptly notify all other parties that it is withdrawing the mistaken designation.

**(4) RESOLUTION OF DISPUTES REGARDING DESIGNATION OF CONFIDENTIAL INFORMATION**

a. In the event that any party contests the designation of Confidential Information or Confidential – Outside Counsel Eyes Only Information, such party shall so inform the other parties to this lawsuit in writing, and all parties shall make good faith efforts to resolve the dispute.

b. In the event that the parties are unable to resolve the dispute regarding designation of Confidential Information or Confidential – Outside Counsel Eyes Only Information, the party contesting the designation may raise the issue in a manner approved by the Court.

c. A party designating a document as Confidential Information or Confidential – Outside Counsel Eyes Only Information must show good cause why the designated information falls under the definition of paragraph 2(a) or 2(b), respectively. Until the matter is resolved by written agreement of the parties or by order of the court, no person in possession of information

designated Confidential Information or Confidential – Outside Counsel Eyes Only Information shall, without prior written consent of the designating party or approval of the court, disclose such information to any person outside the parameters of this order.

**(5) FAILURE TO DESIGNATE**

Any party or third party who fails to designate information as Confidential Information or Confidential – Outside Counsel Eyes Only Information may later do so, and such information shall be treated by the receiving party as being so designated as Confidential Information or Confidential – Outside Counsel Eyes Only Information from the time the receiving party is notified in writing of the designation. The parties agree that the disclosure of Confidential Information or Confidential – Outside Counsel Eyes Only Information by the designating party in producing discovery to the receiving party, regardless of whether the information was designated as Confidential Information or Confidential – Outside Counsel Eyes Only Information at the time of disclosure, shall not be treated as a waiver in whole or in part of the designating party's claim of confidentiality, either as to the specific information disclosed or as to any other information relating thereto or on the same or related subject, and shall not exempt it from the provisions of this Protective Order where notice has otherwise been given that it is Confidential Information or Confidential – Outside Counsel Eyes Only Information. Where a party or non-party changes the designation of confidentiality under this Protective Order, that party or non-party shall promptly furnish the information re-designated in accordance with paragraphs 3.c – 3.e above.

**(6) ACCESS TO CONFIDENTIAL INFORMATION**

Access to Confidential Information designated as "CONFIDENTIAL" shall be limited to, and only to, the following "qualified persons" only, under the following conditions, and shall not be shown to any other persons except as stated below:

- a. Outside attorneys of record to any party in connection with this litigation, and if the attorney of record is a member of a law firm, the employees and staff of the law firm. Before

any such person is permitted access to any of the Confidential Information, such person shall be informed of the existence and contents of this Protective Order.

b. Independent organizations retained by the attorneys to provide litigation support services in this litigation such as jury consultants, trial consultants, graphic artists, database support groups, illustrative exhibit preparation organizations and the like. Before any such person is permitted access to any Confidential Information, the person shall be informed of the existence and contents of this Protective Order, and shall comply with paragraph 8(a).

c. Independent experts and consultants, both testifying and non-testifying, retained in this litigation by the attorneys of record, insofar as the attorneys of record may deem it necessary for the preparation or trial of the litigation to consult with such experts or consultants, provided that any such actual or contemplated expert or consultant is not employed and was not employed by any of the parties hereto, and the conditions set forth in paragraph 8 are fulfilled in relation to any such actual or contemplated expert or consultant.

d. William S. Tremulis, Jeffrey P. Callister, David M. Musket, and Sue Ann Latterman, and limited, designated employees of Ovion, Inc., Musket Research Associates, Inc., and related business entities who are required in good faith to assist in the conduct of the litigation.

e. Court reporters and videotape technicians employed in depositions in the litigation.

f. The Court, its personnel and members of the jury.

g. Such other persons as hereafter may be designated by written agreement in this litigation or by order of the Court.

**(7) ACCESS TO CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY INFORMATION**

Access to information marked “OUTSIDE COUNSEL EYES ONLY” shall be limited to, and only to, those persons listed in paragraph 6 (a), (b), (c), (e), (f), and (g). Persons described in paragraph 6(d) shall not be given access to information marked “OUTSIDE COUNSEL EYES

ONLY”.

**(8) DISCLOSURE PURSUANT TO PARAGRAPHS 6.b – 6.d**

a. Each person referred to in paragraphs 6.b – 6.d hereof to whom Confidential Information or Confidential – Outside Counsel Eyes Only Information is to be given, shown, disclosed, made available or communicated in any way, shall first execute the Declaration, agreeing to be bound by the terms of this Protective Order.

b. At least five (5) business days prior to a party giving, showing, disclosing, making available or communicating Confidential Information or Confidential – Outside Counsel Eyes Only Information to any person referred to in paragraphs 6.b – 6.d, the party shall deliver to all other parties a copy of the Declaration signed by the person to whom Confidential Information or Confidential – Outside Counsel Eyes Only Information is proposed to be disclosed, and a description setting forth the person’s (i) name, (ii) residence and office addresses, (iii) present employer and job description, (iv) consulting activities, (v) relationship to the parties to this litigation, and (vi) a brief job and consulting history for the past three years. If available or reasonably obtainable, the most recent curriculum vitae or resume of an independent expert or consultant shall also be provided.

A party shall be entitled to object to such disclosure to any person referred to in paragraphs 6.b – 6.d within five (5) business days after receipt of the Declaration by stating specifically in writing the reasons why that party believes such person should not receive Confidential Information or Confidential – Outside Counsel Eyes Only Information. The parties shall promptly meet and confer to resolve the dispute over such disclosure.

c. If a party needs further information regarding the person referred to in paragraphs 6.b – 6.d in order to make a decision as to whether to object to that person, such party may request such further information within five (5) business days after receipt of the Declaration. Such party shall then be entitled to object to disclosure to that person within five (5) business days after receipt of the requested information, or receipt of a refusal to provide such information.

d. The objecting party shall have five (5) business days following the receipt of written notification by the opposing party that it is concluding the meet and confer process to move for an order that disclosure not be made to the person, or be made only under certain conditions. The objecting party shall have the burden of establishing grounds for barring the disclosure. The objecting party shall seek to have any such motion presented to the Court at the earliest possible date on the Court's motion calendar. If no such motion is made in such time and manner, then the objecting party shall be deemed to have waived its objection.

e. No disclosure of Confidential Information or Confidential – Outside Counsel Eyes Only Information shall be made to any person referred to in paragraphs 6.b – 6.d until the time for serving objections to that independent expert or consultant has passed, or, in the event that an objection is timely served, until the time for moving the Court has passed, or in the event that such a motion is timely made, until the time as the Court has made a ruling thereon, and then, only in accordance with such ruling.

f. The filing and pendency of objections or motions shall not limit, delay, or defer any disclosures of the Confidential Information or Confidential – Outside Counsel Eyes Only Information to persons as to whom no such objection has been made, nor shall it delay or defer any other pending discovery unless the level of confidentiality bears directly on a party's ability to conduct such discovery.

**(9) USE OF CONFIDENTIAL INFORMATION OR CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY INFORMATION GENERALLY**

a. Confidential Information or Confidential – Outside Counsel Eyes Only Information disclosed pursuant to this Protective Order shall be held in confidence by each person to whom it is disclosed.

b. Information furnished by any party or non-party shall be used by a receiving party solely for purposes of this litigation, shall be protected from any unauthorized or unrelated use, and shall not be used or disseminated by a receiving party for any competitive, commercial, business, research or development purpose. But see Sections 11 and 22.

**(10) USE OF CONFIDENTIAL INFORMATION OR CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY INFORMATION IN CONDUCT OF THIS LITIGATION**

a. Confidential Information or Confidential – Outside Counsel Eyes Only

Information may be used by the attorneys of record in good faith in conducting discovery, provided that the Confidential Information or Confidential – Outside Counsel Eyes Only Information is protected pursuant to the terms and conditions of this Protective Order.

b. Confidential Information or Confidential – Outside Counsel Eyes Only

Information may be disclosed to a witness not already allowed access to such information under this Protective Order if:

(1) the Confidential Information or Confidential – Outside Counsel Eyes Only

Information was previously received or authored by the witness;

(2) the Confidential Information or Confidential – Outside Counsel Eyes Only

Information was produced by or obtained from the witness or from an entity for whom the witness is or was a director, officer, employee, consultant or agent;

(3) counsel for the party designating the material as Confidential Information

or Confidential – Outside Counsel Eyes Only Information agrees that the material may be disclosed to the witness; or,

(4) upon order of the Court for good cause shown.

c. If the Confidential Information or Confidential – Outside Counsel Eyes Only

Information is used in any deposition, then, at the option of the disclosing party, that portion of the proceeding shall be conducted outside the presence of all unqualified persons and any testimony or transcript relating thereto shall be designated as Confidential Information or Confidential – Outside Counsel Eyes Only Information. In the event of disclosure under this paragraph, only the court reporter, videographer, deponent, his/her counsel, and persons to whom disclosure may be made, and who are bound by the Protective Order, may be present during the disclosure or discussion of Confidential Information or Confidential – Outside Counsel Eyes Only Information. Disclosure of Confidential Information or Confidential – Outside Counsel



Eyes Only Information pursuant to this paragraph shall not constitute a waiver of the confidential status of the material so disclosed.

d. Notwithstanding the parties' designation of Confidential Information or Confidential – Outside Counsel Eyes Only Information, any court hearing which refers to or describes Confidential Information or Confidential – Outside Counsel Eyes Only Information shall in the Court's discretion be held in open court with records unsealed unless there is a specific showing that confidentiality is required. The parties have the option to request that the proceeding shall be conducted in camera, out of the presence of all unqualified persons, and any transcript relating thereto shall, subject to the Court's approval, be designated as Confidential Information or Confidential – Outside Counsel Eyes Only Information.

#### **(11) PARTY'S OWN INFORMATION**

The restrictions on the use and dissemination of information established by this Protective Order are applicable only to Information received by a party from another party or from a nonparty. A party is free to do whatever it desires with its own information.

#### **(12) RENDERING ADVICE TO CLIENTS**

Nothing in this Protective Order shall bar or otherwise restrict any attorney from rendering advice to his client with respect to this litigation and, in the course of rendering advice, referring to or relying in a very general way on the examination of Confidential Information or Confidential – Outside Counsel Eyes Only Information, provided, however, that in rendering such advice and in otherwise communicating with his client, the attorney shall not disclose the contents of any Confidential Information or Confidential – Outside Counsel Eyes Only Information produced by another party if that disclosure would be contrary to the terms of this Protective Order.

#### **(13) NO WAIVER**

Other than as specified herein, the taking of or the failure to take any action to enforce the provisions of this Protective Order, or the failure to object to any designation or any such action or omission, shall not constitute a waiver of any right to seek and obtain protection or relief in

this litigation or any other litigation, such right including, but not limited to, the right to claim that any information is or is not proprietary to any party, is or is not entitled to particular protection or that such information does or does not embody trade secrets of any party. The procedures set forth herein shall not affect the rights of the parties to object to discovery on grounds other than those related to trade secrets or proprietary information claims, nor shall it relieve a party of the necessity of proper responses to discovery requests.

**(14) SUBPOENA FROM THIRD PARTIES**

In the event any party or nonparty, which has possession, custody or control of any Confidential Information or Confidential – Outside Counsel Eyes Only Information received from another party or nonparty, receives from a third party a subpoena or other process or order to produce such information, the party or nonparty that received the subpoena or other process or order (1) shall notify the attorneys of record of the party or nonparty claiming such confidential treatment of the Confidential Information or Confidential – Outside Counsel Eyes Only Information sought by such subpoena or other process or order, (2) shall furnish those attorneys of record with a copy of said subpoena or other process or order, and (3) shall cooperate with respect to any procedure sought to be pursued by the party or nonparty claiming such confidential treatment. The party or nonparty asserting the confidential treatment shall have the burden of defending against such subpoena, process, or order. The party or person receiving the subpoena or other process or order will not produce Confidential Information or Confidential – Outside Counsel Eyes Only Information so long as any motion or proceeding initiated to bar or condition disclosure is pending.

**(15) NO PROBATIVE VALUE**

This Protective Order shall not abrogate or diminish any contractual, statutory or other legal obligation or right of any party or person with respect to any Confidential Information or Confidential – Outside Counsel Eyes Only Information. The fact that information is designated Confidential or Confidential – Outside Counsel Eyes Only under this Protective Order shall not be deemed to be determinative of what a trier of fact may determine to be confidential or



proprietary. This Order shall be without prejudice to the right of any party to bring before the Court the question of (a) whether any particular material is or is not confidential, (b) whether any particular information or material is or is not entitled to a greater or lesser degree of protection than provided hereunder; or (c) whether any particular information or material is or is not relevant to any issue of this case, provided that in doing so the party complies with the foregoing procedures. Absent a stipulation of all parties, the fact that information has been designated "CONFIDENTIAL" or "OUTSIDE COUNSEL EYES ONLY" under this Order shall not be admissible during the trial of this litigation, nor shall the jury be advised of such designation. The fact that any information is disclosed, used or produced in discovery or trial herein shall not be construed admissible, or offered in any litigation or proceeding, before any court, agency or tribunal as evidence of or concerning whether or not such information is confidential or proprietary.

**(16) PRIVILEGED MATERIAL**

Nothing in this Order shall be deemed to waive any applicable privilege or immunity, or to limit the relief available to a party claiming that it inadvertently disclosed information subject to any privilege or immunity. Nothing in this Order shall require disclosure of information that is protected by the attorney-client privilege, work product immunity, legal prohibition against disclosure or other privilege or immunity.

**(17) ACCIDENTAL OR INADVERTENT DISCLOSURE OF CONFIDENTIAL INFORMATION OR CONFIDENTIAL – ATTORNEYS EYES ONLY INFORMATION**

In the event of any accidental or inadvertent disclosure of Confidential Information or Confidential – Outside Counsel Eyes Only Information, other than in a manner authorized by this Protective Order, counsel for the party responsible for the disclosure shall immediately notify opposing counsel of all the pertinent facts, and make every effort to prevent further unauthorized disclosure including, retrieving all copies of the Confidential Information or Confidential – Outside Counsel Eyes Only Information from the recipient(s) thereof, and securing the agreement of the recipient(s) not to further disseminate the Confidential Information

or Confidential – Outside Counsel Eyes Only Information in any form. Compliance with the forgoing shall not prevent the designating party from seeking further relief from the court.

**(18) REDACTIONS**

Any producing party may redact from the documents and things it produces matter that the producing party claims is subject to attorney-client privilege, work product immunity, a legal prohibition against disclosure, or other privilege or immunity. The producing party shall mark each document or thing where matter has been redacted with a legend stating “REDACTED FOR PRIVILEGE,” as appropriate, or a comparable notice. Where a document consists of more than one page, at least the first page and each page on which information has been redacted shall be so marked. The producing party shall preserve an unredacted version of each such document. This provision shall not affect any obligation to provide a log of information redacted or otherwise withheld on the basis of attorney-client privilege, work product immunity, a legal prohibition against disclosure, or other privilege or immunity.

**(19) TERMINATION OF LITIGATION**

Within 60 days of the final disposition of the above-entitled case, whether by judgment and exhaustion of all appeals, by voluntary dismissal or by settlement, each party and its attorneys of record:

- (i) Shall destroy or return to the disclosing party, or its attorney of record, the Confidential Information or Confidential – Outside Counsel Eyes Only Information subject to this Protective Order in the possession, custody or control of the receiving party and its attorneys of record and staff;
- (ii) Shall insure that all the Confidential Information or Confidential – Outside Counsel Eyes Only Information subject to this Protective Order in the possession, custody or control of persons who are referred to in paragraphs 6.b – 6.d and 6.g and received such information via the party or its attorneys of record, is destroyed or returned to the disclosing party, or its attorney of record;
- (iii) Shall destroy all notes, memoranda or other documents which contain excerpts

from any of the Confidential Information or Confidential – Outside Counsel Eyes Only Information subject to this Protective Order, and shall ensure that all persons do the same who are referred to in paragraphs 6.b – 6.d and 6.g and received such information via the party or its attorneys of record; and

(iv) Shall deliver to the disclosing party, or its attorney of record, written confirmation that there has been compliance with the terms of this paragraph or that there has not been compliance and the reason for such noncompliance, upon receipt of which the disclosing party may make application to the Court for such further order as may be appropriate.

Notwithstanding the above, outside counsel for each party may retain one copy of all pleadings, discovery requests and responses, transcripts, and deposition and trial exhibits, regardless of whether such documents and things contain Confidential Information or Confidential – Outside Counsel Eyes Only Information. These documents and things shall be maintained in accordance with the terms of this Protective Order.

**(20) ENFORCEMENT OF THIS PROTECTIVE ORDER**

This Protective Order shall remain in force and effect until modified, superseded or terminated on the record by written stipulation of the parties or by order of the Court. This Protective Order shall survive the final conclusion of the litigation and the Court shall have jurisdiction to enforce this Order beyond the conclusion of this litigation.

**(21) VIOLATION OF THE PROTECTIVE ORDER**

In the event any person or party shall violate or threaten to violate the terms of this Protective Order, the aggrieved designating party may immediately apply to obtain injunctive relief against any such person or party violating or threatening to violate any of the terms of this Protective Order. The parties and any other person subject to the terms of this Protective Order agree that this Court shall retain jurisdiction over it and them for the purpose of enforcing this Protective Order.

**(22) MODIFICATION OF THIS PROTECTIVE ORDER**

In the event any party hereto seeks a court order that in any way seeks to vary the terms of this Protective Order, said party shall make such request in the form of a written stipulation, application upon at least ten (10) business days notice to the other party, or noticed motion to all parties that must be served and filed in accordance with local court rules.

Dated: \_\_\_\_\_

\_\_\_\_\_  
United States District Court Judge

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF MASSACHUSETTS  
BOSTON DIVISION**

Musket Research Associates, Inc.,

Plaintiff,

v.

Ovion, Inc.,  
William S. Tremulis, and  
Jeffrey P. Callister,

Defendants.

**Case No. 05-10416 MEL**

Ovion, Inc.,

Counterclaimant,

v.

Musket Research Associates, Inc.,  
David B. Musket, and  
Sue Ann Latterman,

Counterdefendants.

**AFFIDAVIT REGARDING RECEIPT OF CONFIDENTIAL INFORMATION AND  
CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY INFORMATION**

I, \_\_\_\_\_, declare that:

My address is \_\_\_\_\_, and the address of my  
present employer is \_\_\_\_\_

My present occupation or job description is \_\_\_\_\_

\_\_\_\_\_

In addition to my other job functions, I am working as a consultant to

\_\_\_\_\_

My relationship to Plaintiff/Defendant is \_\_\_\_\_

\_\_\_\_\_.

I have received a copy of the Stipulation and Protective Order (the "Protective Order") in this litigation.

I have carefully read and understood the provisions of the Protective Order, agree to be bound by it, and specifically agree I will not use or disclose to anyone any of the contents of any Confidential Information or Confidential – Outside Counsel Eyes Only Information received under the protection of the Protective Order except as permitted under the Protective Order.

I understand that I am to retain all copies of any of the materials that I receive which have been so designated as Confidential Information or Confidential – Outside Counsel Eyes Only Information in a container, cabinet, drawer, room or other safe place in a manner consistent with the Protective Order and that all copies are to remain in my custody until I have completed my assigned or legal duties. I will return all Confidential Information or Confidential – Outside Counsel Eyes Only Information and things which come into my possession or which I have prepared relating thereto, to counsel for the party by whom I am retained. I acknowledge that such return or the subsequent destruction of such materials shall not relieve me from any of the continuing obligations imposed upon me by the Protective Order.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed at \_\_\_\_\_ on \_\_\_\_\_.

\_\_\_\_\_  
[SIGNATURE]

**Ovion Exhibit 2**

**MRA**  
MUSKET RESEARCH ASSOCIATES INC.

July 21, 2004

**CONFIDENTIAL**

Jeff Callister  
President  
Ovion Inc.  
1900 O'Farrell Street  
San Mateo, CA 94403

Dear Jeff:

This letter will confirm the agreement under which Musket Research Associates, Inc. ("MRA") is engaged by Ovion Inc., or any affiliate of Ovion, Inc. (collectively "OVION" or the "Company") to assist the Company as described below.

**1. Engagement**

OVION hereby engages and retains Musket Research Associates, Inc. as a nonexclusive finder/advisor in connection with a proposed private placement of Convertible Preferred Stock of Ovion Inc., including any other debt or equity instrument arising out of this financing effort (the "Placement"), which involves investors solicited by MRA during that effort. The specific services to be provided by MRA and fees to be received will be:

**2. Services**

(a) MRA shall (i) analyze the financial performance and projections of the Company and provide advice regarding the appropriate valuation range for the new equity capital; (ii) assist in the development of presentation materials for investor solicitations; (iii) contact qualified investors and, if acceptable to you or your representative, send the necessary documents ourselves or through your office. Documents sent by the Company at MRA's request should be accompanied by a cover letter and/or business card from MRA, or, if these are not available, a specific reference to our introduction; (iv) after appropriate screening, set up and accompany you to meetings with interested parties as often as scheduling allows; and (v) manage ongoing discussions and coordinate the closings with the investors solicited, or caused to be solicited by MRA.

(b) MRA acknowledges that the offering will be made pursuant to the private offering exemption from registration under Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated thereunder, and that OVION securities are to be offered and sold only to "accredited investors" (as defined in the SEC's Regulation D) who also satisfy any applicable securities laws. Before each closing, OVION will validate these "accredited investors" via a customary suitability questionnaire, copies of which will be provided to MRA upon request.

(c) Prior to sending any descriptive materials to potential investors, MRA will provide OVION a list of these investors so that OVION can make the appropriate securities law filings, if any, in such jurisdictions. MRA will send materials previously approved by OVION when cleared to do so by an OVION representative and will not be responsible for assuring that such jurisdictional

125 CAMBRIDGE PARK DRIVE - 1ST FLOOR - CAMBRIDGE, MA 02140 617-441-8800 FAX 617-441-0855

MRA20844

*Handwritten:* 7/22/04  
7/29/04



filings have been made beforehand. MRA will not make any general solicitation in connection with this financing and will conduct its obligations hereunder in a manner consistent with the requirements of Rule 506.

(d) The potential investors contacted by MRA are subject to acceptance by OVION in its sole and absolute discretion, and OVION is under no obligation to sell any of its capital stock to such parties. MRA shall be deemed to be an independent contractor and shall have no right, power or authority to create any obligations on behalf of OVION.

### 3. Cash Fees

(a) OVION agrees to pay MRA Finder's Fees of seven percent (7%) of the aggregate cash proceeds received by OVION from the Placement to parties solicited by or caused to be solicited by MRA ("MRA Contacts"). "MRA Contacts" shall be those entities set forth on Schedule A of this contract, as updated from time to time, and accepted, as evidenced solely by a countersignature thereto on Schedule A, by the Company. OVION agrees to pay MRA an additional fee of three percent (3%) of the aggregate cash proceeds received by OVION from the Placement to "OVION VC Contacts" and two (2%) of the aggregate cash proceeds received by OVION from the Placement to US Venture Partners. "OVION VC Contacts" shall be those entities designated as "OVION VC Contact" on Schedule B of this contract. Schedule B may be updated from time to time by Ovion in its sole discretion; provided, however, that once an entity is designated as an "OVION VC Contact" on schedule B, such designation may not be removed without the consent of MRA. MRA shall receive no fees for any entity that is not either an MRA Contact or an Ovion VC Contact.

(b) MRA Contacts shall not include (i) current OVION investors and (ii) parties being actively solicited directly by OVION. A complete listing of these two exclusion groups will be provided to MRA by OVION as soon as possible but not later than the signing of this contract and will be attached hereto as Schedule B. At OVION's sole discretion, it may authorize a switch of an investor listed on Schedule B to Schedule A, carrying with it the obligation to pay the fees outlined in Section 3(a) above or a mutually agreeable amount to be specifically listed on both Schedules A and B.

(c) If, during the term of this Agreement, OVION consummates a Placement other than a Placement involving a corporate partner, and the aggregate fees payable to MRA pursuant to Section 3(a) are less than \$225,000, then OVION shall pay to MRA a "Success Fee" equal to \$225,000 less any fees payable to MRA pursuant to Section 3(a).

(d) If, during the term of this Agreement, OVION consummates a merger, acquisition or Placement involving a corporate partner (a "Corporate Transaction") within 90 days of the date hereof and the aggregate fees payable to MRA pursuant to Section 3(a) are less than \$125,000, then OVION shall pay MRA an "Advisory Fee" equal to \$125,000 less any fees payable to MRA pursuant to Section 3(a). If, during the term of this Agreement, OVION consummates a Corporate Transaction between the 90th and the 180th day following the date hereof and the aggregate fees payable to MRA pursuant to Section 3(a) are less than \$225,000, then OVION shall pay MRA an "Advisory Fee" equal to \$225,000 less any fees payable to MRA pursuant to Section 3(a). This Advisory Fee will be payable at the time of the initial closing of whatever financial event OVION does consummate.

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*DM*  
7/21/04  
*WST* 7/29/04  
Mar 10 05 10:34a

Steve Tremulis

9886-465-059

P. 4

(e) OVION will be obligated to pay MRA the same cash fees outlined in Sections 3(a) and 3(b) on any debt or equity related financing entered into with an MRA Contact within the earlier of eighteen (18) months following the final closing of the current Placement or within eighteen (18) months after the termination of this contract.

(f) All payments due to MRA will be made within 10 days of the closing of the financing for which they are payable. Cash or equity will be made out directly to Musket Research Associates, Inc. unless otherwise specified.

(g) The Company will inform MRA immediately if, during the term of this agreement, it engages any additional finders on this Placement, including in such notice a complete description of any fee agreement with such additional finder. If, during the term of this agreement, the Company agrees to pay finders fees in excess of those described in this contract, the fees payable to MRA will be increased to the same level, at the sole discretion of MRA.

#### 4. Expenses

Whether or not the financing contemplated herein is consummated, the Company will reimburse MRA for its reasonable out-of-pocket expenses incurred from this financing, provided such expenses have been approved in advance by OVION, such approval to not be unreasonably withheld. An initial non-refundable payment of \$10,000 as an advance against these expenses will be paid to MRA upon the execution of this contract. OVION-approved expenses incurred by MRA prior to closing will be submitted for reimbursement by OVION and should be paid within two weeks of receipt.

#### 5. Equity Participation/ Fee Substitution

MRA will be allowed, in its sole discretion, to substitute not less than 25% of the cash fees owed to it by OVION, as per Section 3 above for equity or debt instruments in OVION, in whatever form and at whatever value as was paid by the investors contacted by MRA and for which the fees are payable; provided that MRA shall be bound by similar terms and conditions as such investors and provided further that such issuance to MRA or its designee(s) shall comply with applicable state securities laws and shall not preclude OVION's reliance on Rule 506 with respect to the financing. MRA hereby represents that it is an "accredited investor" as defined by Regulation D.

#### 6. Press Releases

OVION will list MRA as participating placement agent in any description of this financing it issues directly (i.e., press release) and will use its own discretion to list MRA similarly in any further communications to the investment community regarding this financing.

#### 7. Termination

This engagement may be terminated by OVION or MRA at any time without cause, upon 10 days written notice to that effect by the other party. However, MRA shall be entitled to the fees described in Sections 3, 4, and 5 above, in the event that, at any time prior to the expiration of 18 months after either the termination of this agreement or the final closing of the current Placement,

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6/15/04

whichever is applicable, a loan, credit facility, or other investment is consummated by OVION with an MRA Contact at the time of termination.

**8. Indemnification**


The Company agrees to indemnify MRA under the terms set forth in Exhibit 1, which is included herein by reference.

Sincerely,

 7/22/04

David B. Musket  
President  
Musket Research Associates

Agreed and Accepted:

  
Jeff Callister  
President  
Ovion Inc.

Date 7/29/04

MRA20847

SCHEDULE A

Approved by \_\_\_\_\_  
Date \_\_\_\_\_

WST  
7/12/04

**OVION Investors Eligible for Full MRA Fees**

[MRA will add names to this list as we screen applicable parties]

**OVION VC Contacts – Partial Fees as Indicated**

|                |        |
|----------------|--------|
| De Novo        | 3% Fee |
| Interwest      | 3% Fee |
| Medventures    | 3% Fee |
| Sprout         | 3% Fee |
| USVP           | 2% Fee |
| Versant        | 3% Fee |
| Vertical Group | 3% Fee |

and all parties and entities affiliated with any group listed above

MRA20848

Don 7/12/04

**SCHEDULE B****OVION Investors NOT Eligible fo Full MRA Fees**

All existing OVION Investors

**OVION VC Contacts – 2% Placement Fee to MRA**OVION VC Contact  
(including affiliates thereof)

OVION Approval

MRA Approval

US Venture Partners

WSTDM**OVION VC Contacts – 3% Placement Fee to MRA**OVION VC Contact  
(including affiliates thereof)

OVION Approval

MRA Approval

De Novo

WSTDM

Interwest

WSTDM

Sprout

WSTDM

Versant

WSTDM

Vertical Group

WSTDM                        

MRA20849

## EXHIBIT 1

Ovion Inc. ("OVION") agrees to indemnify and hold harmless Musket Research Associates, Inc. ("MRA") and each of MRA's officers, directors, agents, employees and controlling persons (within the meaning of each of Section 20 of the Securities Exchange Act of 1934, as amended, and Section 15 of the Securities Act of 1933, as amended)(each of the foregoing, including MRA, being hereinafter referred to as an "Indemnified Person") to the fullest extent permitted by law from and against any and all losses, claims, damages, expenses (including reasonable fees and disbursements for counsel), actions (including shareholder derivative actions), proceedings, investigations (whether formal or informal, or in tort, contract or otherwise), inquiries or threats thereof (all of the foregoing being hereinafter referred to as "Liabilities"), based upon, relating to or arising out of MRA's engagement hereunder or any Indemnified Person's role therein including, without limitation, any liabilities relating to or arising out of the engagement by OVION of any other financial advisor or investment banker; provided, however, that OVION shall not be liable under this paragraph to the extent that it is finally judicially determined by a court of competent jurisdiction that such Liabilities resulted from the willful misconduct or gross negligence of the Indemnified Person seeking indemnification. In connection with OVION's obligation to indemnify for expenses as set forth above, OVION further agrees to advance or reimburse each Indemnified Person for such expenses (including reasonable fees for counsel) as they are incurred by such Indemnified Person; provided, however, that if any Indemnified Person is reimbursed hereunder for any expenses, such reimbursement of expenses shall be refunded by the Indemnified Person who received such expenses to the extent it is finally judicially determined by a court of competent jurisdiction that the Liabilities in question resulted from the willful misconduct or gross negligence of such Indemnified Person.

Each Indemnified Party shall, upon the service of a summons or other initial legal process upon it in any action or suit instituted against it or upon its receipt of written notification of the commencement of any investigation or inquiry of, or proceeding against, it or upon its receipt of other written notification of the assertion against it of any Liabilities, such Indemnified Party will promptly give written notice (hereinafter the "Notice") thereof to OVION (provided that delay in giving such notice shall not relieve OVION of its indemnification obligations hereunder except to the extent, if at all, that it shall have been prejudiced thereby) OVION shall be entitled, if it so elects within fifteen days after receipt of the Notice, by giving written notice (hereinafter the "Defense Notice") to the Indemnified Party, to assume the entire defense of such Liabilities, in which event such defense shall be conducted at the expense of OVION by counsel chosen by it and reasonably satisfactory to the Indemnified Party; provided, however, that if the Indemnified Party reasonably determines (i) that there may be conflict between the positions of OVION and the Indemnified Party in conducting the defense of such Liabilities or (ii) that there may be legal defenses available to the Indemnified Party different from or in addition to those available to OVION, then counsel for the Indemnified Party shall be entitled to participate in such defenses, or conduct the defense to the extent reasonably determined by such counsel to be necessary to protect the interests of the Indemnified Party, and such participation in or separate conduct of such defense shall be covered by the indemnification by OVION hereunder. In any event, any Indemnified Party shall retain the right to participate in the defense of any Liabilities with separate counsel, where the defense of such Liabilities has been assumed by OVION in accordance with the provisions hereof and the circumstances described in clauses (i) or (ii) of the above proviso are not present, but the Indemnified Party shall bear and be solely responsible for its own costs and expenses in connection with any such participation.

If the indemnification or reimbursement provided for hereunder is finally judicially determined by a court of competent jurisdiction to be unavailable to an Indemnified Person in respect to any Liabilities (other than as a consequence of a final judicial determination by such a court of willful misconduct or gross negligence of such Indemnified Person), then OVION agrees, in lieu of indemnifying such Indemnified Person, to contribute to the amount paid or payable by such Indemnified Person as a result of such Liabilities (i) in such proportion as is appropriate to reflect the relative benefits received, or sought to be received, by OVION on the one hand and by such Indemnified Person on the other from the transaction in connection with which MRA has been engaged, or (ii) if (but only if) the allocation provided in clause (i) of this sentence is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in such clause (i) but also the relative fault of OVION and of such Indemnified Person; provided, however, that in no event shall the aggregate amount contributed by the

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WJT 7/29/04

Indemnified Person exceed the amount of fees actually received by his or its affiliate or employer pursuant to such engagement. The relative benefits received or sought to be received by OVION on the one hand and by MRA on the other shall be deemed to be in the same proportion as (i) the gross proceeds raised in the transactions subject to this Agreement bears to (ii) the fees paid or payable to MRA hereunder.

MRA20851

*Don 7/2/04*  
*WY 7/29/04*

**Ovion Exhibit 3**





## Action canceled

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Home &gt; Business &gt; David B Musket

## David B Musket

Data Provided By  
HEMSCOTT

Director at  
**Conor Medsystems, Incorporated**  
Menlo Park, California  
HEALTHCARE / MEDICAL INSTRUMENTS  
& SUPPLIES  
Director since November 1999

Track This  
Person

47 years old

David B. Musket, age 47, has been a member of Conor Medsystems' Board of Directors since November 1999. Since 1996, Mr. Musket has been Managing Director of ProMed Partners, L.P., a healthcare investment fund. Since 1991, Mr. Musket has also been President of Musket Research Associates, Inc., an investment banking firm focused on emerging healthcare companies. Since 1991, Mr. Musket has also been President of DBM Corporate Consulting, Ltd. From 1984 to 1989, Mr. Musket served as a pharmaceutical analyst at Goldman Sachs & Co. Mr. Musket is a member of the Harvard-M.I.T. Health Sciences and Technology Advisory Council. Mr. Musket holds a B.A. in Biology/Psychology from Boston College and spent four years in a doctoral program in Pharmacology and Neurobiology at Cornell University Medical College.

## Cash Compensation (FY December 2004)

|   |            |
|---|------------|
| Salary                                  | n/a        |
| Bonus                                   | n/a        |
| OT Latest FY other short-term comp.     | n/a        |
| HE Latest FY other long-term comp.      | n/a        |
| RE Latest FY long-term incentive payout | n/a        |
| <b>Total</b>                            | <b>n/a</b> |

## Stock Options (FY December 2004)

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**Ovion Exhibit 4**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

|                                   |   |                         |
|-----------------------------------|---|-------------------------|
|                                   | ) | <b>No. 05 10416 MEL</b> |
| MUSKET RESEARCH ASSOCIATES, INC., | ) |                         |
|                                   | ) |                         |
| Plaintiff,                        | ) |                         |
|                                   | ) |                         |
| v.                                | ) |                         |
|                                   | ) |                         |
| OVION, INC., WILLIAM S. TREMULIS, | ) |                         |
| and JEFFREY P. CALLISTER,         | ) |                         |
|                                   | ) |                         |
| Defendants.                       | ) |                         |
|                                   | ) |                         |
| OVION, INC.,                      | ) |                         |
|                                   | ) |                         |
| Counterclaimant,                  | ) |                         |
|                                   | ) |                         |
| v.                                | ) |                         |
|                                   | ) |                         |
| MUSKET RESEARCH ASSOCIATES, INC., | ) |                         |
| DAVID B. MUSKET, and              | ) |                         |
| SUE ANN LATTERMAN,                | ) |                         |
|                                   | ) |                         |
| Counterdefendants.                | ) |                         |
|                                   | ) |                         |

**MUSKET RESEARCH ASSOCIATES, INC.,  
DAVID B. MUSKET AND SUE ANN LATTERMAN'S  
RESPONSE TO OVION, INC.'S FIRST SET OF REQUESTS TO ADMIT (1-12)**

Pursuant to Federal Rules of Civil Procedure 36, Musket Research Associates, Inc., David B. Musket and Sue Ann Latterman (collectively "MRA") respond to Ovion, Inc.'s First Set of Requests to Admit (1-12) as follows:

Request No. 1

Admit that MRA, Musket, and Latterman, individually and collectively, did not contact or solicit AMS on behalf of Ovion or cause AMS to be contacted or solicited on behalf of Ovion.

Response to Request No. 1

Admitted.

Request No. 2

Admit that MRA, Musket, and Latterman, individually and collectively, did not communicate with AMS on behalf of Ovion.

Response to Request No. 2

Admitted.

Request No. 3

Admit that MRA, Musket, and Latterman, individually and collectively, did not set up any meetings between AMS and Ovion.

Response to Request No. 3

Admitted.

Request No. 4

Admit that MRA, Musket, and Latterman, individually and collectively, did not accompany Ovion or its representatives to any meeting with AMS or its representatives.

Response to Request No. 4

Admitted.

Request No. 5

Admit that MRA, Musket, and Latterman, individually and collectively, did not manage any discussions between Ovion and AMS.

Response to Request No. 5

Admitted.

Request No. 6

Admit that MRA, Musket, and Latterman, individually and collectively, did not coordinate the closing between Ovion and AMS.

Response to Request No. 6

Admitted.

Request No. 7

Admit that, as of the dates of the Complaint and the First Amended Complaint, MRA, Musket, and Latterman had no knowledge that Ovion was negotiating with AMS.

Response to Request No. 7

Admitted.

Request No. 8

Admit that, as of the dates of the Complaint and the Amended Complaint, MRA, Musket, and Latterman had no knowledge of the content or substance of any communications between Ovion and AMS.

Response to Request No. 8

Admitted.

Request No. 9

Admit that MRA, Musket, and Latterman, individually and collectively, did not prepare any budgets, forecasts, due diligence materials, presentation materials, or other work product for discussions, communications, or negotiations between Ovion and AMS.

Response to Request No. 9

Objection: This request is vague and ambiguous to the extent it fails to define what is meant by "for discussions, communications, or negotiations between Ovion and AMS." Without

waiving this objection, Musket Research Associates, Inc., David B. Musket, and Sue Ann Latterman (collectively "MRA") state as follows:

MRA admits that it did not prepare any budgets, forecasts, due diligence materials, presentation material, or other work product, with the intent or knowledge that Ovion would use these materials in discussions, communications, or negotiations between Ovion and AMS.

Request No. 10

Admit that MRA, Musket, and Latterman, individually and collectively, publicly disclosed by March 4, 2005 that Ovion was engaged in negotiations to merge with a corporate partner.

Response to Request No. 10

Objection: This request is vague and ambiguous to the extent that it fails to define what is meant by "publicly disclosed." Without waiving this objection, MRA states as follows:

MRA admits that on March 4, 2005 it filed a complaint in the United States District Court, District of Massachusetts, which alleges, among other things, that:

On or about February 17, 2005, slightly more than six months after the Engagement Letter was signed, Ovion announced to MRA that it was entering into a merger and acquisition deal with an unnamed corporate partner.

Request No. 11

Admit that, if Ovion did not use your work product in relation to its communications negotiations, and merger with AMS, you are not entitled to compensation pursuant to the Engagement Letter.

Response to Request No. 11

Denied.

Request No. 12


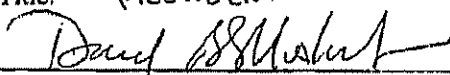
Admit that, if Ovion did not use your work product in relation to its communications negotiations, and merger with AMS, you are not entitled to compensation pursuant to any agreement or understanding with any of Ovion, Mr. Tremulis, and Mr. Callister.

Response to Request No. 12

Denied.

Signed under the pains and penalties of perjury this 22<sup>nd</sup> day of September, 2005.

MUSKET RESEARCH ASSOCIATES, INC.

 9/22/05  
Name: DAVID B. MUSKET  
Title: PRESIDENT  
 9/22/05  
DAVID B. MUSKET

\_\_\_\_\_  
SUE ANN LATTERMANN

Request No. 12

Admit that, if Ovion did not use your work product in relation to its communications negotiations, and merger with AMS, you are not entitled to compensation pursuant to any agreement or understanding with any of Ovion, Mr. Tremulis, and Mr. Callister.

Response to Request No. 12

Denied.

Signed under the pains and penalties of perjury this 22 day of September, 2005.

MUSKET RESEARCH ASSOCIATES, INC.

\_\_\_\_\_  
Name:

Title:

\_\_\_\_\_  
DAVID B. MUSKET

*Sue Ann Latterman*  
\_\_\_\_\_  
SUE ANN LATTERMANN



AS TO OBJECTIONS:

B. A. A.  
Brooks A. Ames (BBO #641192)  
DLA PIPER RUDNICK GRAY CARY US LLP  
One International Place, 21st Floor  
100 Oliver Street  
Boston, MA 02110-2613  
(617) 406-6000 (*telephone*)  
(617) 406-6100 (*fax*)

Arthur S. Beeman (admitted pro hac vice)  
Pamela K. Fulmer (admitted pro hac vice)  
DLA PIPER RUDNICK GRAY CARY US LLP  
153 Townsend Street, Suite 800  
San Francisco, CA 94107  
(415) 836-2541 (*telephone*)  
(415) 836-2501 (*fax*)

Dated: September 22, 2005

**CERTIFICATION OF SERVICE**  
I hereby certify that a true copy of the above  
document was served upon the attorney of record  
for each other party by mail (by hand) on 9/22/05  
B. A. A.

## **Ovion Exhibit 5**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

|                                   |   |                         |
|-----------------------------------|---|-------------------------|
| MUSKET RESEARCH ASSOCIATES, INC., | ) | <b>No. 05 10416 MEL</b> |
|                                   | ) |                         |
| Plaintiff,                        | ) |                         |
|                                   | ) |                         |
| v.                                | ) |                         |
|                                   | ) |                         |
| OVION, INC., WILLIAM S. TREMULIS, | ) |                         |
| and JEFFREY P. CALLISTER,         | ) |                         |
|                                   | ) |                         |
| Defendants.                       | ) |                         |
| <hr/>                             |   |                         |
| OVION, INC.,                      | ) |                         |
|                                   | ) |                         |
| Counterclaimant,                  | ) |                         |
|                                   | ) |                         |
| v.                                | ) |                         |
|                                   | ) |                         |
| MUSKET RESEARCH ASSOCIATES, INC., | ) |                         |
| DAVID B. MUSKET, and              | ) |                         |
| SUE ANN LATTERMANN,               | ) |                         |
|                                   | ) |                         |
| Counterdefendants.                | ) |                         |
| <hr/>                             |   |                         |

**MUSKET RESEARCH ASSOCIATES, INC.,  
DAVID B. MUSKET AND SUE ANN LATTERMANN'S  
ANSWER TO OVION, INC.'S FIRST SET OF INTERROGATORIES (1-2)**

Pursuant to Federal Rule of Civil Procedure 33, Musket Research Associates, Inc., David B. Musket and Sue Ann Latterman (collectively "MRA") hereby respond to Ovion, Inc.'s First Set of Interrogatories (1-2) as follows:

**GENERAL OBJECTIONS**

1. MRA objects to each of the interrogatories to the extent that they seek information protected from discovery by the attorney/client privilege, the work-product doctrine, or other privilege. This General Objection is incorporated into each of the following responses

to Ovion, Inc.'s interrogatories, and the General Objection shall be deemed continuing as to each interrogatory and is not waived, nor in any way limited, by the responses.

2. MRA objects to the Definitions and Instructions to the extent they seek to impose upon MRA obligations that exceed those specified by the Federal Rules of Civil Procedure. MRA will respond to the interrogatories as required by the Federal Rules of Civil Procedure.

### RESPONSES TO INTERROGATORIES

Subject to and without waiving the foregoing General Objections, MRA responds to the individual interrogatories as follows:

#### Interrogatory No. 1

Identify and describe in detail:

- a. all agreements and understandings between any of Ovion, Mr. Tremulis and Mr. Callister on the one hand and any of MRA, Mr. Musket and Ms. Latterman on the other hand;
- b. All documents and things relating to such agreements and understandings; and
- c. All person (sic) with knowledge of such agreements and understandings.

#### Answer to Interrogatory No. 1

a. Musket Research Associates, Inc. ("MRA") and Ovion, Inc. ("Ovion") entered into an agreement dated July 21, 2004 and executed July 29, 2004 (the "Engagement Letter"). The Engagement Letter speaks for itself.

MRA executed the Engagement Letter based on the following agreements and understandings with Ovion:

- Ovion would not pursue a potential corporate partner until after it had made a good faith effort to obtain venture financing.

- Ovion would not use MRA as a “stalking horse” for a corporate transaction.
- Ovion would not use MRA’s research, presentation materials, or other work product to solicit or negotiate with potential corporate partners.
- Ovion would inform MRA if a corporation offered to acquire, fund, or partner with Ovion to assist in the negotiation and financial analysis of any offer.
- Ovion would compensate MRA, commensurate with standard industry practice, to the extent that Ovion used MRA’s research, presentation materials, or other work product to consummate a transaction with a corporate partner.

b. Objection: This interrogatory is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Without waiving this objection, MRA responds as follows:

The Engagement Letter

The Nondisclosure Agreement

c. Robert Hess

Jeffrey P. Callister

William S. Tremulis

David B Musket

Sue Ann Latterman

Interrogatory No. 2

Identify and describe in detail:

- a. all work product on (sic) produced for or on behalf of Ovion including each person and the contribution of each person who contributed to the work product;
- b. all work product that you contend has been used improperly or without authorization by Ovion and how it was improperly used;
- c. all work product that you contend was used by Ovion in communications or negotiations with AMS or was used by Ovion in relation to the merger between Ovion and AMS;
- d. your bases for contending that any of Ovion, Mr. Tremulis, and Mr. Callister has used your work product improperly or without authorization; and
- e. all persons with knowledge of work product produced for or on behalf of Ovion and all documents and things relating to such work product.

Answer to Interrogatory No. 2

Objection: This interrogatory is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Without waiving this objection, MRA responds as follows:

a. MRA prepared budgets, forecasts, plans, due diligence materials, and presentation materials on behalf of Ovion. Sue Ann Latterman was the MRA employee primarily involved in developing this work product. Pursuant to Fed. R. Civ. P. 33(d), MRA will produce documents containing the work product it developed on behalf of Ovion.

b. MRA contends that all of MRA's work product that was used by Ovion to solicit or negotiate with American Medical Systems, Inc ("AMS") or any other potential corporate partner was used improperly and without authorization. MRA will supplement this response once it has completed discovery.

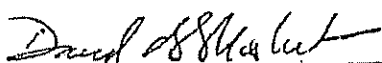
c. Such information is uniquely within the knowledge of Ovion and AMS. MRA will supplement this response once it has completed discovery.


d. If any work product was used to solicit potential corporate partners, it was done improperly and without authorization. MRA will supplement this response once it has completed discovery.

e. Pursuant to Fed. R. Civ. P. 33(d), MRA will produce (a) documents containing the work product it developed on behalf of Ovion, and (b) documents identifying the individuals who received this work product and who have knowledge thereof.

Signed under the pains and penalties of perjury this 22<sup>nd</sup> day of September, 2005.

MUSKET RESEARCH ASSOCIATES, INC.

 9/22/05  
Name: DAVID B. MUSKET  
Title: PRESIDENT

 9/22/05  
DAVID B. MUSKET

\_\_\_\_\_  
SUE ANN LATTERMAN

c. Such information is uniquely within the knowledge of Ovion and AMS. MRA will supplement this response once it has completed discovery.

d. If any work product was used to solicit potential corporate partners, it was done improperly and without authorization. MRA will supplement this response once it has completed discovery.

e. Pursuant to Fed. R. Civ. P. 33(d), MRA will produce (a) documents containing the work product it developed on behalf of Ovion, and (b) documents identifying the individuals who received this work product and who have knowledge thereof.

Signed under the pains and penalties of perjury this 22 day of September, 2005.

MUSKET RESEARCH ASSOCIATES, INC.

\_\_\_\_\_  
Name:


Title:

\_\_\_\_\_  
DAVID B. MUSKET

  
SUE ANN LATTERMANN



AS TO OBJECTIONS:

  
\_\_\_\_\_  
Brooks A. Ames (BBO #641192)  
DLA PIPER RUDNICK GRAY CARY US LLP  
One International Place, 21st Floor  
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*Courtesy of Cooper Surgical/  
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## *Women's Health*

***Stifel, Nicolaus***  
***& Company, Incorporated***

Member SIPC and NYSE

# *New Growth Opportunities in Medical Technology*

Spring 2004

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## WOMEN'S HEALTH/UROGYNECOLOGY – OVERVIEW & INVESTMENT THESIS

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We believe the outlook for the Urology sector, in general, and in particular the Women's Health segment of this market, is becoming increasingly attractive, boosted by favorable demographics, significant product advancement, and changing attitudes towards urologic and gynecological conditions. While the investment history of the sector has been littered with disappointments, we believe the opportunity for companies in this sector to finally realize the promise and potential of the Urology/Women's Health market will become increasingly realizable over the next several years. As a result, we believe that investors should clearly have this sector on their investment radar screen going forward. In recognition of the favorable long-term trends that we believe exist in this market, we recently initiated coverage of three companies that focus on urologic and women's health products, including C.R. Bard (BCR/NYSE/\$98.80-Market Outperform - Required Disclosure: C-2 - See Page 82 for Required Disclosures), American Medical Systems (AMMD\*/NASDAQ/\$25.29-Market Outperform - Required Disclosures: A, C-2 - See Page 82 for Required Disclosures), and Conceptus (CPTS\*/NASDAQ/\$13.42-Market Perform-Required Disclosures: A, C-2 - See Page 82 for Required Disclosures). In addition, several other major players within the medical device sector, including Johnson & Johnson and Boston Scientific, have an established presence in the women's health market, and we believe it only a matter of time before Medtronic views the time as right for adding women's health to its existing urology division. Other well regarded public companies such as Cooper Companies and Cytac have made attractive acquisitions in recent months to further build their presence in this market. Indeed, we believe Women's Health will be an increasingly active area for acquisition activity within the medical device sector over the next several years.

### Overview

We tend to use a broad definition when discussing the overall urology market opportunity, a definition that includes several separate market segments within the urology and gynecology. As a result, as conditions affecting women continue to offer increasingly attractive opportunities for medical device companies, a more accurate definition of the sector at this point would be Urology/Women's Health, or perhaps the somewhat less cumbersome term "UroGynecology." Traditionally, the urology sector has generally been characterized by a focus on just three major urological disorders: incontinence, erectile dysfunction and prostate disease (BPH and prostate cancer). Incontinence and prostate disease have historically represented the most significant market opportunities for companies in this sector, though both markets remain significantly underpenetrated at this point. Despite the benefit of strong demographic trends, the market for device-based therapies for urological and gynecological conditions has remained fairly limited to this point, as treatment options have generally been overly invasive or marginally effective. As a result, pharmaceutical treatments have continued to dominate the market for many urological and gynecological conditions, though many of these treatments are clearly not without problems. In many cases, drugs are only marginally effective, are costly, and can lead to a number of adverse side effects. As a result, we believe pharmaceutical-based therapies present far from an impenetrable barrier to entry for device-based treatments.

The primary motivation behind this report is that we believe that the development of new products and treatment regimens is leading to a breakout in the growth of the UroGynecology market. The development of a variety of new, less invasive, device-based treatments is likely to have a meaningful effect on the women's health side of the overall UroGynecology market, as we will discuss throughout this report. While the current market sizes remain fairly modest, investor awareness of these expanding market opportunities is expanding, boosted by items such as American Medical's eye-opening announcement of 80% growth in its women's health business in the fourth quarter of 2003, and Cytac's recent acquisition of NovaCept just prior to its planned IPO.

**\* Shares of AMMD and CPTS are best suited to aggressive growth investors tolerant of near term volatility.**

As a result, we believe that the Women's Health – or UroGynecology – sector represents an increasingly attractive opportunity for medical device manufacturers over the next several years, as more effective, less invasive device-based therapies are introduced. We believe that these improved treatment options will lead to greater penetration of this meaningful market opportunity. As we are witnessing in other sectors of the Medical Device industry, favorable demographics should provide a very attractive compliment to the growth of this potential market opportunity.

### **Highlights**

In general, the following trends summarize the basis for our long-term investment thesis for companies developing device-based treatments for both urologic and gynecologic conditions:

- The UroGynecology sector presents a significant market opportunity within the medical technology industry, though one that remains largely untapped at this point. The Women's Health segment of this market offers some of the most attractive growth opportunities, in our opinion. As a result, we expect the larger medical device companies such as Johnson & Johnson, Medtronic, and Boston Scientific to show a growing interest in growing their presence in this market over the next few years.
- We believe the long-term prospects for the UroGynecology will be boosted by favorable demographics, including the graying of the "Baby Boomer" generation and continued gains in life expectancy. Importantly, the incidence of conditions such as incontinence, impotence, and prostate problems not only increases with age, some conditions are almost inevitable as a result of the aging process. The longer life expectancy for women helps boost the opportunity in the women's health segment of the market.
- While urologic and gynecological problems affect a huge patient population and result in significant quality of life issues, the market for device-based treatments remains extremely underdeveloped at this point, as only a very small percentage of symptomatic patients actively seek treatment. The embarrassing nature of many of these conditions, unfortunately, keeps many patients from seeking treatment.
- We believe, however, that new product innovation and a lessening of the traditional social stigma attached to urologic and gynecological conditions should result in improved market penetration over the next several years. The key driver of the more "liberal attitude" towards these conditions has been the tremendous success of Viagra over the past 5 years, the subject of a very aggressive and wildly successful advertising campaign. Viagra has dramatically altered the public perception of the ultimate taboo condition of erectile dysfunction, for example, and we believe there will increasingly be spillover into other conditions such as incontinence.
- Importantly, the development of significantly more effective and less invasive device-based treatments for many of these conditions puts medical device companies in a much stronger position to take advantage of this trend. Similarly, newer devices also position this sector to benefit from the growing trend towards office-based treatments, away from the hospital setting. We believe this easier access to more effective, less invasive forms of treatment should combine to help drive the long-term growth of the urology and women's health markets.
- Reimbursement has, historically speaking, been a recurring problem for companies in the urology market. In an about face, however, reimbursement has been surprisingly robust for a growing number of products and procedures in the urology/gynecology sector, however, which should help drive market growth going forward. Last fall, for example, CMS implemented significant 40%+ increases in reimbursement for office-based treatments for Benign Prostatic Hyperplasia (BPH), which we believe will prove to be a significant boost to the development of this market. Similarly,

treatments for Abnormal Uterine Bleeding recently enjoyed an even more substantial hike in reimbursement (50%+), which should help drive the growth of that market. Bottom line, we believe the sector will continue to benefit from the development of cost effective, less invasive, superior solutions to conditions traditionally treated with either drug therapy or surgery.

This report focuses, in particular, on the Women's Health side of the overall Urology/Gynecology market, with an in depth discussion of the various market opportunities, the companies that stand to benefit, and the new products that will help drive the development of these new markets. Specifically in this report, we discuss the markets and key products for the treatment of incontinence, transcervical sterilization, as well as abnormal uterine bleeding and uterine fibroids. A future report will cover the "male" side of the urology sector, including advancements in the treatment of both prostate cancer and BPH (enlarged prostate).

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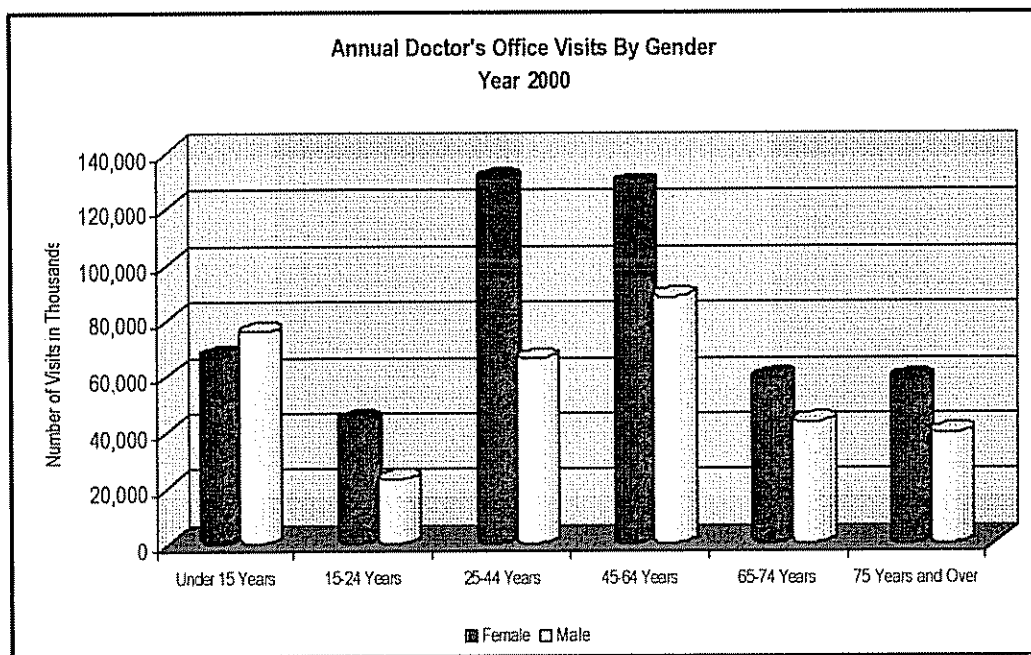


## FOCUS ON WOMEN'S HEALTH

### *Women Offer New Growth Opportunities for Medical Device Companies*

In terms of size and growth rate, the market for women's health products dwarfs its male counterpart at this point. The reasons are fairly obvious. While women represent 52% of the population, they currently account for approximately 2/3<sup>rd</sup>s of all health care expenditures in the U.S., or roughly \$500 billion each year. According to a recent report published by Medtech Insight, women account for approximately 61% of all doctor's appointments and 59% of all prescription drug purchases.

There are a number of factors that contribute to these disproportionate statistics, in our opinion, the most obvious being factors specific to a woman's basic physiology, along with the fact that women have longer life expectancies than men. According to recent figures from the U.S. Department of Health and Human Services, the average life expectancy of a woman is 79.5 years versus 74.1 years for men, meaning that the majority of our elderly population is heavily biased towards women. For example, the overwhelming majority of long-term care recipients are women, and women represent 3 out of every 4 of nursing home residents and 2 out of every 3 home health care service recipients. These statistics have vast implications for the opportunity in women's healthcare, as the demand for healthcare services and products has a strong correlation with aging. This can be especially true with many urologic and gynecologic conditions.



Source: U.S. Department of Health and Human Services. Centers For Disease Control and Prevention.

In addition, many of these conditions, such as pregnancy, infertility therapy, abnormal bleeding, and incontinence require multiple visits to the doctor over a specific period of time. Women require frequent interaction with physicians for the management of pregnancy, childbirth, infertility issues, incontinence, contraception, and menopause. In its 2002 annual report, Cooper Companies cites data from the U.S.



Census Bureau indicating that approximately 90 million women between the ages of 15 and 64 made nearly 120 million visits to an OB/Gyn during 1999. Of these visits, approximately 70 million were directly related to specific gynecological conditions. Prospective estimates published by the Census Bureau suggest that by the year 2010, annual visits to OB/Gyn physicians will rise to 132 million, with approximately 84 million of these visits relating to gynecological conditions. These figures reflect, in part, the favorable impact of demographics, as the "Baby Boomer" generation continues to age. As the population continues to grow older, more women will require medical attention for gynecological disorders, creating an expanding growth opportunity for companies in the Women's Health sector.

Let's get a bit more specific. Not surprisingly, women incur a significantly greater number of conditions and disease states that require medical intervention than do men, directly or indirectly as a consequence of the childbirth process. For example, pregnancy and childbirth can cause damage to the female pelvic floor, leading to stress urinary incontinence, requiring eventual intervention by a gynecologist or urologist. In addition to issues related to reproduction, women are also more susceptible to osteoporosis, a condition that can lead to a host of severe and debilitating orthopedic problems. Statistics show that osteoporosis poses a significant threat to nearly 30 million Americans, with approximately 10 million living with the disease. Estimates suggest that 80%, or 8 million, of these individuals are women. While clearly there are many other conditions such as BPH or Prostate cancer that are specific to the male population, women unfortunately have "exclusive rights" to many more medical issues to contend with. This is illustrated by the fact that during the year 2000, females accounted for approximately 60% of all hospital discharges. While childbirth creates something of a distorting factor within this data, a National Discharge Survey still indicates that females have higher hospitalization rates for genitourinary, digestive system, musculoskeletal system, cancer, endocrine, nutritional, metabolic, and immunity disorders.

#### ***Women Taking Charge***

Women also typically tend to be much more proactive in researching and seeking appropriate medical therapies, including preventative care, another factor that we believe will boost the development of the Women's Health market. During 2000, for example, females made approximately 105 million preventative/non-illness office visits, as compared to only 50 million such visits for men. Just as important, women generally also tend to be much more willing than men to share their experiences with friends and co-workers, which could be another important factor in the development of the women's health market. This can be an especially important factor with potentially embarrassing conditions such as incontinence, topics that men tend to be particularly private about. As a result, women can provide invaluable word of mouth advertising for companies in the Women's Health market segment. This tends to be non-existent in the male-specific markets for urologic conditions.

Finally, in what we believe will be a critically important factor in the development of the Women's Health market, a rapidly growing percentage of gynecologists, both in active practice and currently in training, are women. For example, the AAGL (American Association of Gynecologic Laparoscopists) recently indicated that more than 80% of current residents-in-training are women. We believe this ongoing trend will increasingly fuel the movement towards newer, less invasive gynecological treatments, and the movement of procedures out of the hospital and into the office setting.

## OVERVIEW OF MARKET OPPORTUNITIES IN WOMEN'S HEALTH

The next few paragraphs offer just a brief overview of the Women's Health market segments featured in this report. As shown in the figure below, device manufacturers have just scratched the surface of most of these potential market opportunities, evidenced by the modest current markets relative to the considerably more substantial theoretical market opportunities. The body of the report, meanwhile, offers greater detail on both the markets, the companies participating in these particular product categories (both public and private), and the devices that we expect to be factors in the growth of these markets.

| Market Segment              | Affected Population (U.S.) | Current Device Patient Population | Current Market Size (millions) | Potential Device Patient Population | 2008 Potential Market Size (Millions) | Players  |
|-----------------------------|----------------------------|-----------------------------------|--------------------------------|-------------------------------------|---------------------------------------|--|
| Stress Urinary Incontinence | 8-13 Million               | 85,000                            | \$30 Million                   | 500,000                             | \$150 Million                         | Bard, Boston Scientific, Protein Polymer, and Multiple Private Companies                     |
| Bulking Agents              |                            | 130,000                           | \$150 Million                  | 375,000                             | \$420 Million                         | American Medical, Bard, Boston Scientific, Mentor, Cook and Caddera Medical                  |
| Slings                      |                            |                                   |                                |                                     |                                       |  |
| Abnormal Uterine Bleeding   | 2.5 Million                | 240,000                           | \$180 Million                  | 775,000                             | \$700 Million                         | American Medical, Boston Scientific, Cytac, Johnson & Johnson and Multiple Private Companies |
| Uterine Fibroids            | 6 Million                  | 15,000 - 25,000*                  | \$4 Million                    | 1 Million**                         | \$500 Million                         | BioSphere Medical, Boston Scientific, and Vascular Control Systems                           |
| Transcervical Sterilization | 700,000 - 800,000          | 8,000                             | \$8 Million                    | 210,000                             | \$200 Million                         | Conceptus and Multiple Private Companies   |

Source: Stifel Nicolaus Estimates

\* UAE procedures only

\*\* Includes a mix of UAE, Uterine artery occlusion, and global ablation

### Incontinence

According to estimates published by the Agency for Health Care Policy and Research, more than 13 million Americans are affected by urinary incontinence, and approximately 1 million new cases are diagnosed annually. Other sources, however, suggest that this number may actually be closer to 25 million people. Either way, it is a significant market opportunity, and approximately \$15 billion is spent annually in the U.S. on incontinence diagnosis, products, and patient care. In fact, more than \$20 billion is spent each year just on adult diapers and pads. While UI can affect both women and men of all ages, the condition most commonly occurs in women between the ages of 30 and 60. Women, in fact, are considered more than twice as likely to experience UI as men, primarily due to factors relating to pregnancy and childbirth, as well as the overall configuration of the female urinary system. Unlike several other urologic conditions, there isn't necessarily a direct correlation between the aging process and urinary incontinence, though changes in the urinary tract, such as pelvic floor relaxation, can accelerate with aging. Not surprisingly, the condition is most prevalent among the elderly, though the aging of the Baby Boomer generation is helping expand the market as lady Boomers move past their child bearing years. Estimates published by the National Institute of Health (NIH) suggest that urinary incontinence affects as many as 30% of people between the ages of 15 and 64 years in some fashion, and more than 50% of nursing home residents. In fact, urinary incontinence is one of the primary factors leading to the decision to place a loved one in a nursing home.

### ***Abnormal Uterine Bleeding***

Abnormal uterine bleeding (AUB), also known as menorrhagia or dysfunctional uterine bleeding (DUB), is a condition that affects approximately one of every five women between the ages of 35 and 50 years, or roughly 8 million American and 20 million women worldwide. In the United States, estimates suggest that as many as 1/3 of all visits to gynecologists, a whopping 2.5 million visits, are directly related to AUB. Women who suffer from AUB can experience symptoms such as intense cramping, abdominal and deep pelvic pain, exhaustion, dyspnea (shortness of breath), fainting spells, and angina or chest pain. In addition to these problems, approximately 2/3 of women with abnormal uterine bleeding are anemic. Because of the potential for embarrassment associated with menorrhagia, many women become reclusive and avoid social interaction at all costs. In addition to causing severe emotional distress, the condition also has serious implications on a woman's ability to participate in routine activities. We believe the growing influence of female gynecologists will be especially important in the growing market for global endometrial devices, as the movement away from very invasive procedures such as hysterectomies.

### ***Uterine Fibroids***

Uterine fibroids are the most common type of tumor in women, affecting 30% to 40%, or approximately 10 million American women between the ages of 25 and 45. Each year, approximately 5.5 to 6.0 million American women visit their gynecologist for treatment of uterine fibroids, placing a total cost of approximately \$1.2 billion on the U.S. healthcare system. Uterine fibroids are benign, or non-cancerous, tumors that grow on or within the uterine walls. While uterine fibroids themselves are relatively painless and asymptomatic, their presence in the uterus can cause severe problems for a woman. Specifically, multiple small or few large fibroids can press against adjacent organs in the pelvic region, creating "bulk symptoms" such as intense pelvic pain and pressure, low back pain, excessive uterine bleeding, elevated urinary frequency, anemia, constipation, hemorrhoids, and weight gain. According to medical literature, fibroids are symptomatic in approximately 10% to 20% of women. Uterine fibroids are often the root cause of abnormal uterine bleeding, accounting for approximately 30% of all reported cases. Finally, women who have large fibroids also carry a higher risk of infertility and miscarriage.

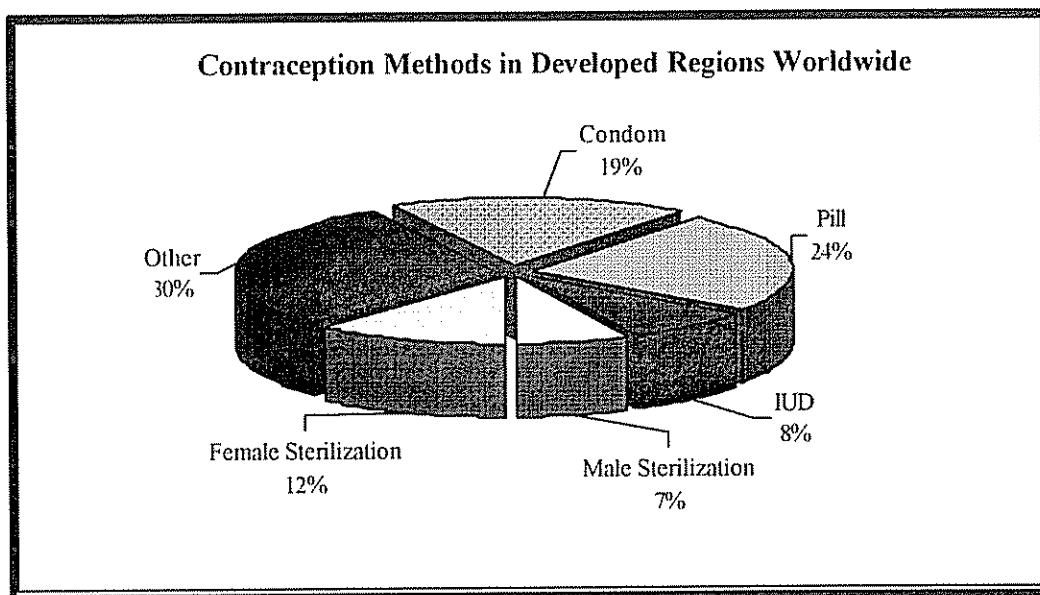
### ***Transcervical Sterilization for Permanent Contraception***

According to a study published by the Centers for Disease Control (CDC), approximately 64% of the nearly 60 million fertile women in the U.S. use some form of birth control. While women and men have a variety of non-permanent options when it comes to choosing contraception, including birth control pills, condoms, IUD's, diaphragms, and hormone injections, overall dissatisfaction and/or non-compliance with these methods can quickly cause to be these products to be ineffective or discarded. For women, some of these products cause side effects such as severe mood swings, bloating, and weight gains that they are generally unwilling to live with on a daily basis. As a result, it is clear that women and couples desire more effective and more diverse contraceptive options. This notion is supported by a study published by Family Planning Perspectives, which indicates that approximately 44% of American women change contraceptive methods within 12 months of first use, and 64% switch methods within a 2-year time period.

In total, approximately 21 million American women continue to rely on non-permanent contraceptive methods such as oral contraceptives and implants. Annual expenditures for non-permanent birth control total approximately \$6.5 billion and \$4.0 billion in the U.S. and international markets, respectively. Within this group of women in the U.S., approximately 7.5 million have at least 2 children, making them candidates for permanent options such as tubal ligation. While the typical tubal ligation procedure is considered to be safe and effective, it is an invasive surgical procedure that is associated with a number of risks. We believe that the risks of the procedure, along with a host of other side effects, such as extended recovery times, abdominal pain, and the possibility of infection, scarring, and re-operation clearly point to the fact there is a need for a safer and more comfortable alternatives. To eliminate the risks and drawbacks that are commonly associated with surgical tubal ligation, physicians and medical device manufacturers have focused on developing less invasive, transcervical methods of permanent sterilization.

## THE CHANGING MARKET FOR PERMANENT CONTRACEPTION

According to data published in the National Survey of Family Growth, approximately one-half of all pregnancies in the US are unintended, with the majority of these pregnancies occurring while a woman is using some form of contraception. Data from the same study shows that 1.3 million, or 22% of the more than six million pregnancies during 1996 ended in abortion. On a worldwide basis, estimates suggest that the number of unintended pregnancies total approximately 79 million per year, or 25% of all pregnancies. Of these 79 million pregnancies, nearly 33 million were terminated by scheduled abortion. According to a study published by the Centers for Disease Control (CDC), approximately 64% of the nearly 60 million fertile women in the US use some form of birth control. While women and men have a variety of non-permanent options when it comes to choosing contraception, including birth control pills, condoms, IUD's, diaphragms, and hormone injections, overall dissatisfaction and/or non-compliance with these methods can quickly cause these products to be ineffective or discarded. For women, some of these products cause side effects such as severe mood swings, bloating, and weight gains that they are generally unwilling to live with on a daily basis. As a result, it is clear that women and couples desire more effective and more diverse contraceptive options. This notion is supported by a study published by Family Planning Perspectives, which indicates that approximately 44% of American women change contraceptive methods within 12 months of first use, and 64% switch methods within a 2-year time period. Despite these statistics, approximately 21 million American women continue to rely on non-permanent contraceptive methods such as oral contraceptives, implants, and injectables. Within this group of women, approximately 7.5 million have at least 2 children, making them likely candidates for permanent methods of contraception, such as tubal ligation. We estimate that total annual expenditures for non-permanent birth control are approximately \$6.5 billion and \$4.0 billion in the US and international markets, respectively. We estimate that the current US and International markets for permanent contraception, which includes both tubal ligation and vasectomy, are approximately \$1 billion and \$2.5 billion, respectively.



Source: United Nations Population Division, 1998



### ***Permanent Contraception***

Permanent methods such tubal ligation for women and vasectomy for men are highly effective for long-term contraception, though these procedures obviously carry the risks associated with surgical procedures. While it may be difficult to believe, tubal ligation is actually the most popular method of contraception among women throughout the world. Estimates suggest that more than 10 million women in the US and over 100 million women worldwide have undergone tubal ligation as a means of permanent birth control. There are approximately 700,000 to 800,000 tubal ligations performed each year in the US, and more than 13 million are performed worldwide on an annual basis. According to the CDC, approximately 39% of American women who use some form of contraception have chosen tubal ligation as their primary protection against pregnancy. On a worldwide basis, tubal ligation accounts for approximately 33% of all women using contraception. This is higher than any other method of contraception (on a cumulative basis), including birth control pills, condoms, patches, intrauterine devices, diaphragms, and male sterilization. The popularity of this procedure is attributable to the fact that tubal ligations are an extremely effective form of contraception, relatively simple to perform, and they are cost effective. Additionally, tubal ligations do not inhibit sexual drive, require no patient compliance or pharmaceutical regimen, and do not cause any awkwardness that can diminish the mood or sexual experience since there is nothing to take or insert prior to intercourse. While there are clearly many positives associated with tubal ligation, the largest drawback to this method of contraception is that it requires an incision and general anesthesia, which elevates the risks of the procedure.

There are two primary methods of performing a surgical tubal ligation, either by Laparotomy/mini-laparotomy or Laparoscopy. Both of these methods are highly effective, producing 1-year success rates of at least 99.5%. Tubal ligation via Laparotomy is an open surgical procedure that requires a relatively large incision (2-5 inches for laparotomy / 2 inches for mini-laparotomy) and therefore, the use of general anesthesia. This procedure is only performed on an "in-patient" basis in a hospital operating room. Due to the invasiveness of this method of tubal ligation, complication rates are higher, hospital stays are longer, and the postoperative recovery period is longer than those required by laparoscopic surgery. While open surgery has become somewhat overshadowed by the introduction of laparoscopic sterilization, the procedure continues to be utilized for patients who are contraindicated for laparoscopy, such as obese individuals. Today, the majority (90%) of tubal ligations are performed via laparoscopy, which involves inserting a laparoscope (a minimally invasive scope) through a very small incision near the navel, and a second incision above the pubic hairline for the insertion of a surgical probe. Once the laparoscope is in the body and the pelvic area is visualized, the surgeon may use one of many methods, including cauterization, clips, or tubal rings, to actually seal the fallopian tubes. A typical laparoscopic procedure can be performed on an "outpatient" basis either in a hospital setting or at an ambulatory care or surgical center, and only lasts about 30 to 45 minutes. Post-operative recovery involves an approximate four to five hour stay at the hospital or surgical center immediately following the procedure, and four to six days of light recovery before returning to normal day-to-day activities. While the laparoscopic method is far less invasive than open laparotomy, more than 90% of these procedures require the use of general anesthesia, a factor that substantially increases the risk profile of the operation.

Tubal ligation remains the global "gold standard" in permanent contraception, due to the fact that it is a highly effective form of birth control, boasting a long-term success rate of more than 99%. While the procedure's effectiveness clearly provides an advantage over other non-permanent birth control methods, tubal ligation does have several drawbacks. The most significant drawback of tubal ligation is that it requires general anesthesia, a factor that substantially increases the risk profile of the procedure. In fact, according to data collected from the landmark CREST study, the use of general anesthesia raises the risk of complication to nearly five times that of a procedure using only local anesthesia. While generally rare, serious complications associated with general anesthesia include large fluctuations in blood pressure, aspiration, arrhythmia, myocardial infarction, stroke, and in very rare cases, death. Patients who undergo general anesthesia may also experience nausea or vomiting, have a sore throat from the breathing tube that is inserted during the procedure, and may feel tired or achy for a few days following surgery. In addition to increasing patient risk, the use of general anesthesia requires the presence of an anesthesiologist, which adds to the overall cost of the procedure.

Another drawback is that a tubal requires an incision and substantial dissection to gain access to the fallopian tubes, which creates post-operative pain and scarring. Abdominal incisions can lead to complications such as infection and bleeding, and in rare cases, blunt and sharp dissection can cause damage to blood vessels and nearby organs such as the bowels, bladder, uterus, and cervix. Generally, complications are quite rare, occurring in only 2% to 5% of all cases (depending on the surgical approach). When complications do occur, however, they can be serious and potentially lead to hospitalization and unintended surgeries. Since tubal ligation requires an incision and general anesthesia, recovery from the surgery typically spans a 4 to 10 day period, and on average, 1 to 2 days of this recovery period involves bed rest. This scenario can be especially difficult for busy or working women, who cannot afford to take extended periods away from work, as well as for mothers of young children. Finally, in contrast to other methods of contraception, tubal ligation is a relatively expensive procedure, with total costs ranging from \$2,000 to \$6,000.

### ***Transcervical Sterilization***

While the typical tubal ligation procedure is considered to be safe and effective, it is an invasive surgical procedure that is associated with a number of risks. We believe that the risks of the procedure, along with the extended recovery time, abdominal pain, and the possibility of infection, scarring, and re-operation clearly point to the fact there is a need for a safer and more comfortable alternative to tubal ligation. To eliminate the risks and drawbacks that are commonly associated with surgical tubal ligation, physicians and medical device manufacturers have focused on developing less invasive, transcervical methods of permanent sterilization. The transcervical approach utilizes a hysteroscope to access the fallopian tubes through the uterus rather than through an abdominal incision. We believe that this less invasive method presents many significant advantages to the patient, the physician, and health care facility. Clearly the most important advantage is that it is safer than surgical methods, in large part because it requires only local anesthesia. While this is an important advantage for all patients, it is especially beneficial for high-risk patients such as those who suffer from heart disease or who are obese. These conditions are often contraindications for tubal ligation, and often prevent patients from choosing sterilization as a form of contraception. Since the approach is non-invasive and requires no incision, transcervical sterilization reduces patient discomfort, allows for quicker recovery times, reduces morbidity, and eliminates the possibility of abdominal scarring. A shorter recovery time significantly reduces the amount of time a patient may have to miss work and allows for a quick return to normal daily activities. From the perspective of the health care facility and payers, we believe transcervical sterilization presents a significant cost saving opportunity. Eliminating surgery and general anesthesia from the procedure enables the physician to perform the procedure in an office setting, potentially reducing overhead expenses relating to medical staff and medical equipment.

Sounds like a rather obvious choice, doesn't it? Unfortunately, while the notion of transcervical sterilization may seem relatively simple, it is actually very difficult to successfully and permanently block the fallopian tubes. During the past several years, there have been a multitude of unsuccessful attempts at developing an effective transcervical sterilization procedure. There are currently a number of different transcervical sterilization technologies in development, however, which look extremely promising. Some of these methods include insertable quinaerine pellets, Erythromycin sterilization, and a handful of intratubal ligation devices. To date, the only company with FDA approval to market a transcervical sterilization product in the U.S. is Conceptus, maker of the Essure Micro-coil Tubular Occlusion System, though others should hit the market over the next couple of years.

### ***Conceptus – The Essure Micro-Coil Tubular Occlusion System***

Essure is the first minimally invasive, non-surgical permanent birth control device to receive FDA approval for commercial sales in the US market. The device, approved in late 2002, consisting of a polyethylene terephthalate (PET) fiber laced into the center of a soft, pliable micro-coil, is non-invasively implanted into the fallopian tubes to cause occlusion of the fallopian tubes and ultimately, sterilization. The stent-like portion of the device, which is constructed of Nitinol, a material commonly used in coronary and peripheral vascular stents, anchors itself within the tubal lumen, and the PET fiber promotes tissue in-growth. This

**Essure Vs. Tubal Ligation**

|  | <b>Essure</b>  | <b>Tubal Ligation</b>  |
|--|--|--|
| <b>Procedure Type:</b>                     | Transcervical (non-incisional) sterilization                           | Laparotomy or Laparoscopy requiring abdominal incisions or punctures |
| <b>Setting:</b>                            | Hospital Outpatient, Ambulatory surgical center, or physician's office | Hospital Inpatient/Outpatient or Ambulatory surgical center          |
| <b>Anesthesia:</b>                         | Local and/or I.V. sedation   | General  |
| <b>Effectiveness:</b>                      |  |  |
| <b>1-year:</b>                             | 99.81%   | 99.45%   |
| <b>2-year:</b>                             | 99.78%   | 99.16%   |
| <b>3-year:</b>                             | 99.8%  | -  |
| <b>10-year:</b>                            | Data not available   | 99.15%   |
| <b>Average Procedure Time:</b>             | 35 minutes   | 30-45 minutes (laparoscopy)  |
| <b>Average Postoperative Recovery:</b>     | 45 minutes   | 2 - 4 hours  |
| <b>Average Return to Daily Activities:</b> | 1 - 2 days   | 4 - 10 days  |
| <b>Average Procedure Cost:</b>             | \$1,500 - \$2,000  | \$2,000 - \$6,000  |

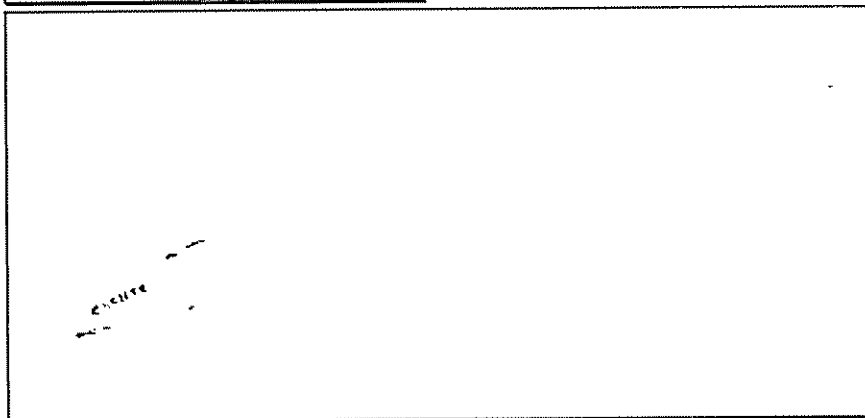
Source: Conceptus, Inc.

tissue in-growth is what eventually occludes the fallopian tubes. Essure is transcervically inserted using a hysteroscope and a catheter delivery system during a procedure that typically lasts less than 30 minutes. Because it typically takes about three months for this in-growth to cause full occlusion, women are required to use alternative methods of contraception until the device reaches full efficacy. A patient can typically leave the medical facility within 45 minutes of having the procedure, and can resume normal activity levels within one or two days. Unlike surgical tubal ligation, the procedure does not require an abdominal incision or general anesthesia, drastically lowering the risk profile of the operation. As a result, the Essure procedure has the potential of being performed in the doctor's office, though only very small percentages

are done in that setting at this point. With an average procedure cost of \$1,500 to \$2,000 and physician reimbursement that is equivalent to tubal ligation, we believe that Essure is an attractive and cost-effective alternative for permanent contraception.



### ***The Essure Micro-Coil Insert and Delivery Catheter***



*Source: Conceptus, Inc.*

#### **Essure's Clinical Data is Convincing.**

CPTS has conducted two large, multi-center human clinical trials, a Phase II study and a Pivotal trial, to evaluate the safety and efficacy of the Essure device, and to support the device's approval application to the FDA. Collectively, these studies have yielded device data for more than 600 women in the U.S., Europe, and Australia. Combined data from both of these studies is quite convincing, showing no pregnancies for women who have relied on the Essure device for permanent contraception over a two-year time period. In statistical terms, the data shows that Essure is 99.78% effective in preventing pregnancy at a two-year follow-up interval, which compares quite favorably to the two-year efficacy rate of 99.16% produced by tubal ligation. Moreover, 99% of the women who have relied on Essure for contraception have rated their long-term satisfaction with the device as "good" to "excellent" and 96% of these women have stated that they would recommend the procedure to a friend. Essure's Pivotal Trial, which involved device placement attempts in 518 women, produced a first attempt bi-lateral placement rate of 86%, and a second attempt placement rate of 90%. Further, data from this trial indicated that 92% of its Essure patients who were employed outside the home were able to return to work within one day following the procedure. Finally, the data shows that of these women who experienced successful placement, 97% have been able to successfully rely on Essure for permanent contraception. Three-year safety and efficacy data for Essure was recently presented at the American Association of Gynecological Laparoscopists meeting, which was held during November 2003. This data showed a three-year statistical effectiveness rate of 99.8% for the Essure



device CPTS has recently filed an application with the FDA to update its device labeling to include this favorable information

### **Essure Drawbacks**

While its minimally invasive approach and strong short-term clinical data have convinced us that Essure stands a very good chance of eventually becoming the standard of care in permanent birth control, there are a few drawbacks associated with the device that we believe are contributing to weaker than expected adoption of the device in the domestic marketplace since FDA approval

### **Essure Requires Hysteroscopic Experience.**

One of Essure's primary drawbacks is the fact that the procedure requires a gynecologist to have experience with a hysteroscope, a very small telescope that is used to visualize the uterine cavity during minimally invasive gynecological procedures. Based on information provided by CPTS, we estimate that only about 15% to 20%, or 5,000 to 7,000 of the approximately 35,000 practicing OB/GYN's in the U.S. routinely use a hysteroscope in day-to-day practice. Hysteroscopy requires a technical proficiency that is relatively difficult to master, and many gynecologists have opted not to invest the time to learn this skill. In addition, hysteroscopy requires a sterile environment and a significant investment in supplies and capital equipment. While these factors have been a factor in the slow initial uptake of the Essure procedure, especially in the office setting, we believe that growth potential of this and other less invasive procedures could lead more gynecologists to learn and incorporate hysteroscopy into their respective practices. We also believe that the high cost of liability insurance, which has caused many obstetricians to discontinue their delivery practices, could eventually push physicians towards less-invasive hysteroscopic procedures as a means of generating future revenues. We believe that the gynecologists already trained and equipped to perform hysteroscopic procedures provide CPTS with ample market opportunity in the near-term. Over the long-term, we expect that market dynamics will increase the number of hysteroscopically trained gynecologists and provide CPTS with a growing customer base.

### **Bi-lateral Placement Rates**

Essure's labeling indicates first attempt bi-lateral placement rates of only 86%. This means that physicians performing the procedure will have at least one failed placement attempt out of every 10 Essure cases performed. While this rate climbs to about 90% for the second attempt, and more recent studies suggest placement rates as high as 92%, the FDA's current approval prevents the Company from providing this updated data on its packaging. Essure is a single-use product, meaning that the physician must open another package in order to re-attempt placement of the device following a failed placement. Because the facility bears the cost of each \$970 device that is either placed or attempted to place, we believe that some physicians will not become fully comfortable performing the procedure until the Company is able to show higher bi-lateral placement rates. It should be noted that placement failure is not necessarily a shortcoming of the Essure device itself. Approximately 5% of women have at least one naturally occluded fallopian tube that prevents successful device placement. In other women, anatomical factors such as having lateral fallopian tubes make it very difficult to place the insert on the first attempt. The Essure device also causes tubal spasms in a small number of women. These spasms of the fallopian tubes can lead to device expulsion during the procedure, resulting in a failed placement attempt. Physicians have begun administering NSAID's (non-steroidal anti-inflammatory drugs such as Advil) prior to device placement, which has been shown to significantly reduce the incidence of tubal spasms, and thus boost placement rates. CPTS also recently launched an improved, more flexible, "coil-catheter" that has been shown in Australian studies to increase bi-lateral placement rates to 95%. While this catheter is currently approved for U.S. distribution, CPTS cannot change its packaging label to reflect these improved placement rates without formal approval from the FDA. The Company is currently gathering additional clinical data needed to support this claim, and intends to file a PMA supplement with the FDA later in 2004.

### **Hysterosalpingogram (HSG) Required to Confirm Sterilization**

Because it takes approximately 3 months for the Essure micro-insert to fully incorporate into the body, patients are required under Essure's current FDA approval to undergo a hysterosalpingogram (HSG) 90 days following the procedure to confirm that the device has succeeded in blocking the fallopian tubes. An

HSG is a non-invasive diagnostic X-ray (fluoroscopic) procedure that enables physicians to visualize the uterus and fallopian tubes. Since it is able to show the point of blockage in a fallopian tube, this device is commonly used in infertility evaluation procedures. The procedure, most typically performed by a radiologist, involves injecting radioactive contrast, or dye, into the uterine cavity using a transcervical approach. Once injected, this dye flows through the uterine cavity and into the fallopian tubes. If the tubes are not obstructed, then the dye will flow through the tubes and spill into the abdominal cavity. If they are blocked, however, the dye cannot advance forward, thus indicating a successful occlusion. While the HSG procedure is a relatively simple outpatient procedure that typically lasts less than 30 minutes, the pressure associated with injecting dye into the uterine cavity can cause heavy cramping during and after the procedure that can be very painful for many women. Unfortunately, this cramping is more intense and painful if the fallopian tubes are blocked, as they are following a successful Essure procedure. Realizing that the HSG component of the procedure could cause apprehension among women who are interested in Essure, CPTS requested during its FDA approval process that the agency allow for different visualization methods to be used to confirm sterilization. While both a flat pelvic X-Ray and ultrasound methods have been proven effective in this capacity are used routinely in conjunction with Essure in the international markets, the FDA currently requires the use of an HSG in the domestic market because this test was used during Essure's clinical trials. To remove the HSG requirement from Essure's label would require CPTS to undergo a clinical study for submission to the FDA. Because CPTS would have to devote financial and human resources to this process, we do not believe that removing the HSG requirement is a priority for CPTS at this time. We do expect, however, that the Company will revisit this issue in the future.

#### **Physicians Remain Skeptical About Essure**

It is well known within the medical device industry that physicians are by nature a conservative group. This fact holds especially true for gynecologists, who are typically very slow to incorporate new technology into their day-to-day practices. Persuading these individuals to abandon procedures with which they have significant long-term experience, and are comfortable performing, in favor of a new, relatively unproven technology can be a very difficult task for any medical device manufacturer, not to mention an up-and-coming Company with limited brand recognition. Physicians typically demand to see a variety of peer reviewed publications to provide third party validation of CPTS' clinical studies, as well as extensive long-term clinical data before committing to a new technology. Given the fact that gynecologists have been performing tubal ligations for more than 3 decades with success rates exceeding 99%, we believe that this skepticism is clearly an issue for Essure.

Despite these shortcomings, we believe that with its non-invasive delivery, quicker recovery period, and proven clinical efficacy, Essure provides women with a compelling alternative to tubal ligation for permanent birth control. While these factors may serve as stumbling blocks for CPTS in the near-term, we believe that the Company will be successful in working through these obstacles over the long-term, and ultimately position Essure as the standard of care in permanent contraception.

#### **Reimbursement Critical to Market Acceptance of Transcervical Sterilization**

Obtaining third party reimbursement for both the device and the related physician fee is obviously a key component of Essure's chances for success in the U.S. marketplace. Unlike many devices used in cardiac and orthopedic procedures, which are typically implanted in patients over the age of 65, the Essure device is most commonly used in patients who are in their thirties or forties. As a result, the Essure procedure is not reimbursed by Medicare, meaning that payment for the procedure typically rests with health insurance companies. While virtually all of these companies currently reimburse hospitals and physicians for the cost of a tubal ligation procedure, they are under no direct obligation to pay for Essure. Today, Essure is reimbursed under the American Medical Association's reimbursement codes #58615 and #58579, which provide reimbursement to both the physician and the facility. Notably, reimbursement to the physician under these codes is roughly equivalent to tubal ligation, so there is no disincentive to incorporate Essure into everyday practice. While at this point it appears that the majority of physicians have been successful in securing favorable reimbursement for the Essure procedure, there have been instances where patients have

been diverted to tubal ligation because their insurance companies will not pay for Essure. Conceptus management, for example, recently indicated that at least 520 patients who were scheduled to receive the Essure device during the fourth quarter of 2003 were denied coverage by their insurance companies. We suspect that many of these women went on to have tubal ligation rather than waiting for their insurance company to issue a favorable reimbursement decision for Essure. Since a national CPT code for reimbursement does not go into effect until January 1, 2005, the current process of obtaining reimbursement commitments from third-party insurers is inefficient, and presents an inconvenience to the physician's staff, with each individual case requiring a pre-approval from the patient's insurance company. We believe that this process has presented a significant challenge to CPTIS, and has been a contributing factor to the slow uptake of Essure in the domestic market since FDA approval was obtained. In our opinion, both physicians and facilities will not actively pursue the adoption of the Essure procedure until they have confidence that they can receive coverage without having to actively petition an insurance company. CPTIS has devoted significant financial and human resources to remedy this situation, with the intent of gaining favorable national coverage decisions from third-party insurance companies.

While the Company has made significant strides in securing third party reimbursement for the Essure procedure since the product's approval in November 2002, many insurance companies will not commit to coverage until they have longer-term data and peer reviewed literature that prove the economic benefits that Essure brings to the healthcare system. CPTIS can do nothing more than wait for long-term data, though a number of favorable peer reviewed articles have been published in medical journals during 2003, including studies published by the prestigious *Green Journal* and *Human Reproduction*. We expect that these existing publications, along with more that are scheduled for release during 2004, will provide insurance companies with the third party validation they need to issue national decisions for Essure reimbursement.

In addition to driving the coverage process through physician and consumer demand, CPTIS is also actively lobbying employers, who have significant influence and leverage with large third-party health insurers, to push for national Essure reimbursement. CPTIS intent with this campaign is to prove to employers that the Essure procedure, which only requires 1 to 2 days before returning to normal activities, is a cost effective alternative to tubal ligation, which typically requires 4 to 10 days of recovery.

To date, the Company has approximately 124 million "patient lives" under coverage, with favorable coverage decisions coming from the likes of Blue Cross/Blue Shield national, who has implied that it will cover the Essure procedure based on medical necessity, Blue Cross / Blue Shield regional plans, Aetna, HealthMark, and WellPoint. Essure has also gained coverage from Medicaid in 10 states, which accounts for approximately 9 million covered lives. The Company is currently in the process of lobbying United Healthcare, Humana, Kaiser, Cigna, and the remaining Medicaid states, which collectively could represent more than 75 million lives, for favorable coverage of the device.

### ***Recently Announced CPT and HCPCS Codes Point to More Favorable Reimbursement Environment During 2005***

CPIS announced on March 4, 2004 that the American Medical Association (AMA) CPT Editorial Panel will establish a Category I CPT code for CPIS's Essure procedure. This code will cover the physician fee component of the Essure procedure in all treatment settings. While this code will establish direct reimbursement for Medicare and Medicaid patients only, it will also affect reimbursement from private payers, since these agencies typically rely on the amounts established by CMS as a guideline for their own reimbursement practices. This code and the specific dollar amount associated with the procedure are expected to be published in the Federal Register during October, and implementation will take place on January 1, 2005. While private payers are not bound to this code, the fact that its establishment was sponsored by the American College of Obstetricians and Gynecologists adds a clear sense of legitimacy to the procedure that is unlikely to go unnoticed by the private insurers.

At the end of March 2004, Conceptus announced that the Centers for Medicare and Medicaid Services (CMS) granted a temporary HCPCS (Healthcare Common Procedure Coding System) code for the Essure procedure that would provide reimbursement of the device itself in the outpatient/ambulatory and office settings. This temporary code, which became effective on April 1, 2004, provides reimbursement for the Essure device in treating Medicare and Medicaid patients. Again, given the fact that Essure is not a procedure that is generally applicable to women over the age of 65 years, this code would only directly affect reimbursement for Medicaid patients. More importantly, this newly issued code is essential for gaining device reimbursement from private payers since they commonly use CMS issued codes as a guideline for their own reimbursement decisions. While the actual reimbursement amount associated with this code is unknown at this point, management is confident that it will cover the full cost (\$970) of the device.

The Company had applied for an HCPCS code last year and was rejected by CMS, with the agency informing Conceptus that the device would have to be reimbursed under a general facility fee. Determined that this facility fee would not be enough to cover the cost of the Essure device, Conceptus appealed the decision and was successful, as evidenced by this recent decision. Conceptus' ultimate intention is to drive Essure business into the physician's office, and the establishment of a specific device-related reimbursement code is a key ingredient to achieving this goal. As it stands today, approximately 80% of Essure procedures are performed in the hospital setting. For these cases, actual device reimbursement has not been an issue, and has in fact been a relatively smooth process. The procedure is generally grouped within one code that covers everything except the physician's fee, including items such as the Essure device itself, anesthesia, hospital room, nursing and other miscellaneous items that are utilized during the procedure. The remaining Essure cases are performed in the outpatient or ambulatory surgical settings, which account for approximately 15% of cases, or in the doctor's office, which represents just 5% or so of cases at this point. Obtaining device reimbursement for these settings has been a problem for physicians in the past, creating a major hurdle for those who wish to perform the Essure procedure. The significance of the HCPCS code is that it will enable physicians to fully recover the cost of the Essure device so that they can bring the Essure procedure into their offices. When used in conjunction with the forthcoming CPT code, the physicians should, in theory, be able to secure reimbursement for both performing the procedure and for the device itself. Again, it is important to note that private insurance companies are not bound by these codes; rather the codes are typically utilized by these payers as a guideline to establish their own coverage levels.



### ***Essure Reimbursement Summary***

#### **Category 1 CPT Code**

The CPT code will serve to cover the physician fee component of the Essure procedure in all treatment settings. While this code will establish direct reimbursement for Medicare and Medicaid patients only, it will also affect reimbursement from private payers, since these agencies typically rely on the amounts established by CMS as a guideline for their own reimbursement practices. The code and its specific dollar amount are expected to be published in the Federal Register during October, and implementation will take place on January 1, 2005.

#### **HCPCS Temporary Code**

The temporary HCPCS code covers the actual cost of the device for Medicare and Medicaid patients in the outpatient or ambulatory surgical center and office settings, but not in the hospital. Hospitals have their own coding systems that group all costs associated with Essure, except the physician fee, into one payment code. As with the CPT code, we believe that the HCPCS code will serve as a reimbursement guideline for private insurers.

#### **Together: CPT + HCPCS Codes**

Taken together, the existence of both codes will enable physicians to be reimbursed for both the cost of the device and the procedure fee in the outpatient/ambulatory and office settings. The full effect of this combination will not be realized until the CPT code is implemented on January 1, 2005.

### ***Competition***

#### **Window for Essure is Shrinking, With New Devices on the Horizon**

As the only commercially available transcervical sterilization product on the market, CPTIS does not compete directly with a specific product or company at this point. Rather, the Essure device competes with the tubal ligation procedure itself. This can be viewed as a significant positive for CPTIS, since there is an obvious demand for a superior alternative to tubal ligation from both physicians and consumers alike. In the long-term, we believe that the clear advantages of transcervical sterilization will ultimately allow transcervical sterilization products like Essure to surpass tubal ligation as the standard of care in permanent contraception. In the near-term, CPTIS still faces the challenge of convincing gynecologists that have been performing tubal ligation for more than 3 decades to adopt Essure and incorporate the procedure into their practices. In many cases, these physicians are typically reluctant to abandon their current practice patterns in the absence of extensive long-term clinical data and peer reviewed publications that give them compelling reason to do so. Combined with the issues involved with obtaining third party reimbursement, as discussed in the preceding section, we believe 2005 now looks much more like the potential "breakout" year for Essure than does 2004. While the significant market opportunity that we believe exists for an attractive, effective alternative to tubal ligation makes this wait bearable for CPTIS shareholders, the window of opportunity for CPTIS as the only approved transcervical sterilization device continues to shrink.

#### **Adiana (Private)**

In terms of direct competitive threats, CPTIS' closest competitor is Adiana, Inc. (Private, Redwood City, CA), whose tubal occlusion device utilizes a two-step, transcervical approach to permanent sterilization. The Adiana device consists of a control unit and a delivery catheter, which is equipped with a radio frequency (RF) electrode and a porous, permanent biomaterial that is implanted into the fallopian tubes. During the Adiana procedure, the physician uses a hysteroscope to guide the catheter into the fallopian tubes, where RF energy is delivered for approximately 60 seconds, causing superficial destruction to the tubal epithelium. Following this process, a matrix of permanent biomaterial is placed in the newly created lesion. The initial RF therapy stimulates tissue ingrowth of this matrix, which ultimately becomes space filling and occlusive. Like the Essure procedure, the procedure is not immediately effective, and requires

the performance of a hysterosalpingogram (HSG) to document occlusion at approximately twelve weeks following the device's initial placement

Adiana began enrolling women for its FDA clinical trial during November 2002. This trial is very similar in design to the Conceptus FDA trial, and will evaluate 500 patients at 15 centers throughout the United States. Adiana's trial is a single-arm study that will use data from the CREST study as a historical control and pregnancy as its primary endpoint. Under its FDA Investigational Device Exemption approval, Adiana was required to enroll 100 patients and submit data to the agency before proceeding to the next 400 women. The FDA was looking to ensure that Adiana met three primary criteria before proceeding to a larger patient population. Specifically, the agency required that Adiana produce 200 patient months of reliance data, less than 2 pregnancies, and an acute bi-lateral access rate of 85% or better for this first cohort of patients. The Company met these criteria during September 2003, presenting the FDA with 300 patient months of reliance, zero pregnancies, and a bilateral placement success rate of 96%. Adiana is actively enrolling and treating the remaining 400 women for its trial.

As of February 2004, 312 patients at 14 sites have been enrolled in Adiana's clinical study, with approximately 65 having been excluded for various reasons during pre-screening. Of the 247 who were actually taken into the operating room for hysteroscopy, 9 patients were excluded due to having a single ostium, Asherman Syndrome, adenomyosis, or other abnormal uterine pathology, leaving 238 actual placement attempts. Successful bilateral placement was achieved in 227 of these 238 patients, implying a first attempt bilateral access rate of approximately 95.3%. At present, 140 patients have reached the end of the infarction stage with 100% of HSG's demonstrating tubal occlusion. Enrollment for the trial is expected to be completed during the second quarter of 2004, suggesting that all of the three-month HSG studies would be complete by August 2004. Assuming a one-year follow-up from the last HSG, we expect the Company to file a PMA application with the FDA during August 2005, with our expectation of FDA approval by mid-2006.

#### **Ovion (Private)**

Ovion, Inc. meanwhile, has developed a transcervical tubal occlusion device known as the Eclipse Permanent Contraceptive Device that is similar in design to Conceptus' Essure product. Like Essure, the Eclipse product consists of a fiber matrix encapsulated by a stent that anchors the device in the fallopian tubes. Over a short period of time, this matrix promotes tissue in-growth that blocks the fallopian tubes and causes sterilization. During the past several years, Ovion and Conceptus have been in disputes over the intellectual property that surrounds their similar approaches to permanent tubal occlusion. The two companies recently settled these disputes, with Conceptus conceding to Ovion through a settlement, and agreeing to license the company's technology for its Essure product. Under the terms of the settlement, CPTS gains an exclusive worldwide license to all of Ovion's patents pertaining to the Essure device. In exchange for these patents, CPTS has agreed to pay Ovion a \$2 million prepaid cash royalty payable during the fourth quarter of 2003 and \$2 million fee payable in CPTS stock during the first and second quarters of 2004. Additionally, CPTS has agreed to pay Ovion a royalty of 3.25% on cumulative net sales exceeding \$75 million. This royalty payment has a 10-year duration. While Ovion has been very selective with respect to information about the product and the clinical process, we believe the company has focused its efforts on addressing some of the perceived shortcomings of the Essure device. Specifics are hard to come by, though enhancing the deliverability of the product is clearly one of Ovion's goals, with the intention of making the product easier to deliver in an office-based setting. Ovion management would not comment on the potential timing of FDA approval and market introduction, though we do believe the company is well into the human clinical process.

#### **Microsulis**

Finally, recognizing the potential synergies that exist between permanent sterilization and endometrial ablation, Microsulis has developed a microwave tubal occlusion system that is based on its proven microwave ablation technology. Rather than using an implantable coil system or stent, which can be somewhat difficult to place in the fallopian tubes, Microsulis' Microwave Tubal Occlusion device deposits microwave energy into the base of the fallopian tubes to cause permanent occlusion. While the product is only in feasibility studies at this point, the company intends to incorporate this treatment into its MFA

global endometrial ablation therapy, resulting in a combination product that would provide women with the convenience of ablation and sterilization in one short office or outpatient visit

#### **Other Competitors**

In addition to devices from Adiana, Ovion, and Microsulis, we are also aware of a handful of additional transcervical sterilization products that are currently in various stages of development. Berkeley Applied Science and Engineering (San Francisco, CA) is currently developing a potentially reversible, transcervically-delivered tubal occlusion device that employs a nickel-titanium stent to block the fallopian tubes. The objective of this product is to cause occlusion without creating significant tissue damage to the fallopian tubes, so that reversal of the procedure could be an option for the patient over the long-term. Also in development is the Intratubal Ligation Device (ILD) from Biomedical Engineering Solutions. The ILD procedure employs either hysteroscopic or blind placement of an O-ring around a tissue peduncle to occlude the fallopian tubes.

### ***Concomitant Global Endometrial Ablation and Transcervical Sterilization Presents Interesting Opportunity***

Because the entire interior lining of the uterus is destroyed, pregnancy following an endometrial ablation procedure can be very dangerous for both a mother and her fetus. Therefore, women who undergo an endometrial ablation procedure are required to have some form of permanent contraception shortly after the surgery. Currently, the most common choice for permanent contraception is tubal ligation, an invasive procedure that requires the woman to schedule an additional appointment and to endure another recovery period within a couple of months of her original ablation surgery. A solution to this problem, and one that we expect will ultimately become a very important component of the women's health market, is for physicians to perform global endometrial ablation and transcervical sterilization together on a concomitant basis. The combination of these procedures would provide women with the opportunity to undergo two minimally invasive procedures at the same time, rather than having to space them out over time. We believe that this combination represents an important therapeutic option for working women who cannot afford to take time away from the office, and for mothers of young children who have to schedule childcare during visits to the physician. During October 2003 Conceptus and J&J/Gynecare announced an exclusive strategic marketing alliance under which J&J would co-promote the Essure and ThermoChoice therapies as a concomitant procedure, a move that we believe legitimizes the concept of combining the two procedures.

However, while the advantages of performing these two procedures on a concomitant basis are clear, there are a number of reasons to believe that gynecologists will not be quick to incorporate this combined procedure into their everyday practices. In our opinion, reimbursement represents the primary obstacle for this procedure, at least in the near-term. As we understand it, the concomitant performance of these two procedures unfortunately results in a loss of revenue for the physician due to the manner in which reimbursement is currently structured. At this point, if the physician performs the two procedures at the same time, he/she is only reimbursed for performing one hysteroscopy. However, by splitting the two procedures and performing them on a separate basis, the physician can receive payment for performing a hysteroscopy in each case, and therefore benefits from the separation of the two. In addition to reimbursement, it is also not clear as to how the combination of these therapies will affect efficacy and placement rates for the transcervical sterilization component of the procedure. In the case of the Essure and ThermoChoice, there is little information available as to what order the procedures will be performed and what the implications will be if one is performed before another. If the Essure device is placed before performing the ablation procedure, then the micro-coils, which hang down into the uterine cavity, could potentially interfere with or puncture the ThermoChoice balloon. In addition, the ThermoChoice balloon could also displace the Essure inserts, and render them ineffective. On the other hand, if the ThermoChoice procedure is performed prior to placement of the Essure device, the ablation procedure could make the Essure procedure more difficult, and adversely affect the bi-lateral placement of the occlusion device. Essure's current U.S. labeling states that first-attempt bi-lateral placement rates are only 86%, a figure that was achieved under normal circumstances by some of the most experienced surgical gynecologists in the world. It would seem that by ablating the entire interior lining of the uterus, the physician would have

visualization, and would therefore have an easier time performing the Essure procedure. However, we are not yet convinced that the Essure procedure will be any easier to perform following global ablation, especially when combined with the ThermoChoice system. Keeping in mind that the primary criticism of the ThermoChoice device is that it reaches less than optimal conformity with the cornual horns in the uterus, we would not expect the entrance to the fallopian tubes to be as clean as the rest of the uterine wall. Because the ThermoChoice system cannot typically reach deep into the cornual region, it is possible that the device could either leave undamaged endometrial tissue behind, or the device could heat the tissue but not completely destroy it, which could inflame the tissue, causing it to swell. In either case, we do not believe that this would result in the optimal environment for placing the Essure device. While admittedly, this is largely supposition on our part, there is no publicly available data showing what the effects on bi-lateral placement are for the Essure procedure when it is used following a ThermoChoice ablation treatment. We believe that physicians will be hesitant to combine these two procedures without having solid evidence showing that the outcomes of each procedure will not be compromised.

Looking forward, we believe that forthcoming devices such as the Aadiana and Ovion Eclipse may be better suited than Essure for concomitant use with global ablation devices. Specifically, we believe that because these devices are smaller and do not leave any materials hanging down into the uterine cavity, physicians could perform the sterilization first, and then follow with the ablation procedure without having any adverse effect on bi-lateral placement rates. Additionally, because the Aadiana device does not contain any metal parts, we believe that it will be well positioned to be used concomitantly with any type of energy source, including microwave and radiofrequency energy sources.



## **Glossary**

**Abdominal Hysterectomy:** Surgical removal of the uterus through an incision in the abdomen

**Abnormal Uterine Bleeding:** Condition characterized by excessive and prolonged menstrual bleeding. Clinically defined as menstrual period that lasts for more than eight days or which produces blood loss in excess of 80 milliliters per menstrual cycle. The condition is also referred to as “menorrhagia”

**Amenorrhea:** Complete cessation of menstrual bleeding

**Bladder Neck Suspension:** A surgical procedure indicated for patients suffering from minor or only moderate stress incontinence. During the procedure, the surgeon uses sutures to elevate the urethra and bladder neck by attaching them to the pelvic bone or adjacent structures

**Bulking Agents:** Compounds that are non-invasively injected around the bladder neck and urethra to strengthen or “bulk up” the urinary sphincter to prevent leakage. Bulking agents can be natural or synthetic, and consist of materials such as autologous fat, Teflon, bovine collagen, pyrolytic carbon beads, and silicon

**Cervical Os:** The narrow opening of the cervix which enables the passage of menstrual blood out of the body and which dilates during childbirth. Instruments are passed through the cervical os during transcervical diagnostic or operative hysteroscopy procedures

**Cervix:** The narrow, neck shaped portion of the uterus

**Diagnostic Hysteroscopy:** A short and relatively minor diagnostic hysteroscopic procedure that is typically performed to investigate gynecological conditions such as infertility, uterine fibroids, recurrent miscarriage, and bleeding disorders.

**Dilation and Curettage (D&C):** A diagnostic procedure that involves passing a curette into the uterus to scrape the endometrium away from the uterine walls

**Dysmenorrhea:** Painful menstrual cramps

**Endometrial Ablation:** A less invasive alternative to hysterectomy that utilizes a resectoscope and electro-cautery tools, such as a loop or roller ball, to minimally invasively ablate, or destroy the functional layer of the endometrium to prevent abnormal uterine bleeding (AUB)

**Endometrium:** The highly vascular mucous membrane that serves as the interior lining of the uterus. The endometrium is the layer that supports and provides nourishment to a developing embryo during pregnancy, and is also the layer that sheds away during menstruation

**Eumenorrhea:** A normal menstrual period

**Fundus:** The portion of a hollow organ that is at the furthest point from the opening. In the case of the uterus, the fundus is the wide, top wall of the uterus

**GnRH Agonist:** Drug used to inhibit the release of the follicle-stimulating (FSH) and luteinizing hormones (LH) that are produced by the pituitary gland and stimulate estrogen production in the ovaries. Cutting off the production of estrogen creates a menopausal effect in women, and therefore significantly reduces the volume of blood flow during menses

**Global Endometrial Ablation Device:** Less invasive and less skill dependent devices that can ablate endometrial tissue in a simple and uniform manner. These new devices produce clinical efficacy that is similar to traditional endometrial ablation while avoiding the use of fluid distention and general anesthesia,

reducing intra-operative complications such as uterine perforation, and significantly reducing operative times

**Hypomenorrhea:** A short or very light menstrual period

**Hyponatremia:** A condition that arises when the sodium level in the bloodstream falls below 135 milliequivalents per liter of blood, creating an electrolyte imbalance in the body. Symptoms of the condition which can progress rapidly if unnoticed or untreated by the physician, include pulmonary edema, bradycardia, anemia, hypotension, seizures, brain damage, congestive heart failure, convulsions, coma, and in severe cases, death.

**Hysterectomy:** Surgical removal of the uterus

**Hysteroscope:** An endoscope that is employed for direct visualization of the uterine cavity

**Hysteroscopy:** Diagnostic or operative procedure that utilizes a fiberoptic telescope that is transcervically inserted into the uterus

**Intramural Fibroid:** Intramural fibroids grow within the myometrium, or inner layer of the uterine wall, and represent the most common type of fibroid. These fibroids are commonly associated with "bulking symptoms" as well as abnormal uterine bleeding.

**Laparoscopically Assisted Vaginal Hysterectomy (LAVH):** Surgical procedure that employs laparoscopic instruments to remove the uterus through the vagina

**Laparotomy:** General term for abdominal surgery.

**Laparoscopy:** Less invasive surgical procedure in which a small scope is inserted through a tiny incision in the abdomen

**Laparoscopic Tubal Ligation:** Procedure that involves inserting a laparoscope (a minimally invasive scope) through a very small incision near the navel, and a second incision above the pubic hairline for the insertion of a surgical probe. Once the laparoscope is in the body and the pelvic area is visualized, the surgeon may use one of many methods, including cauterization, clips, or tubal rings, to actually seal the fallopian tubes.

**Leiomyomata:** See uterine fibroid

**Menorrhagia:** Condition characterized by excessive and prolonged menstrual bleeding. Clinically defined as menstrual period that lasts for more than seven days or which produces blood loss in excess of 80 milliliters per menstrual cycle. Also referred to as "abnormal uterine bleeding".

**Myoma:** See uterine fibroid

**Myomata:** See uterine fibroid

**Myomectomy:** A surgical procedure that involves cutting the fibroids out of the uterine cavity while preserving the uterus. Myomectomy is often considered an appropriate therapy for younger women suffering from uterine fibroids who want to preserve their capacity for childbearing.

**Myometrium:** The muscular middle layer of the uterine wall

**Mixed Incontinence:** A combination of stress and urge incontinence

**Operative Hysteroscopy:** Hysteroscopic procedure that incorporates surgical tools, such as cautery tools, resection loops, and forceps into a special hysteroscope called a resectoscope, which enables the physician to perform minimally invasive surgery within the uterine cavity under direct visualization

**Overflow Incontinence:** A type of incontinence that occurs when weak bladder muscles cannot contract properly, causing urine to overflow and leak out of the body. Overflow incontinence is a common symptom of benign prostate hyperplasia (BPH), and therefore is more prevalent among men.

**PBAC Score:** A scoring system used to diagnose abnormal uterine bleeding and determine to what extent a woman suffers from the condition

**Pessary:** A vaginally inserted, ring-shaped device that suppresses urine leakage by providing support to the urethra and bladder neck

**Sling Suspension:** Implantation of a sling device to raise and support the bladder neck and urethra. Once implanted, the suspension sling essentially "lifts up" a weakened pelvic floor to its original position, thereby defeating the forces of gravity and stopping leakage. The sling procedure is considered by urology practitioners to be the "gold standard" treatment for stress incontinence.

**Stress Incontinence:** A type of urinary incontinence in which small amounts of urine leakage occur during activities that place pressure on the abdomen, such as laughing, coughing, sneezing or exercise. Stress incontinence is primarily attributable to weakening pelvic floor muscles which cause urethral hypermobility and intrinsic sphincter deficiency.

**Submucosal Fibroid:** Submucosal fibroids, which only represent about 5% of fibroids, grow from the interior wall of the uterus into the uterine cavity. These fibroids can be painful and lead to abnormal uterine bleeding and infertility.

**Subserosal Fibroid:** Subserosal fibroids grow on the outside of the uterus, and cause intense pain as they grow large and place pressure on surrounding organs such as the bladder, bowel and intestine. These types of fibroid, which can either have a wide or a thin stalk-like base, are the second most common fibroid.

**Supra-pubic (top-down) Approach:** A surgical method of implanting a sling whereby insertion needles are passed through two very small stab incisions in the abdomen and one small incision in the vagina. The specialized curvature of the needles employed during this procedure helps the surgeon to maintain constant traction along the posterior aspect of the pubic bone, ensuring that the device stays within the "zone of safety" in the space of retzius in order to avoid perforating the bladder or any adjacent vasculature.

**Tension Free Vaginal Tape (TVT):** Originally developed by Johnson & Johnson's Gynecare division during the mid-1990's, tension-free tape is a synthetic mesh sling that is anchored by friction rather than screws, sutures, or tacking devices. Rather than keeping constant tension on the urethra, tension free devices provide some slack and only tighten when abdominal "stress" from a movement such as a cough or sneeze is placed on the urethra.

**Transcervical:** Through the cervix

**Transobturator Sling Implantation Approach:** A surgical method of implanting a sling in which insertion needles are passed through two incisions at the obturator foramen and are advanced with rotation of the wrist along the posterior surface of the pubic ramus, ensuring that the device maintains its presence in the "zone of safety" and away from the retropubic space where bowel, bladder, and vascular damage is likely to occur.

**Transvaginal (bottom-up) Approach:** A surgical method of implanting a sling whereby insertion needles are passed through an incision in the vagina.

**Tubal Ligation:** Surgical procedure to ligate, or cut the fallopian tubes in order block passage of eggs from the ovaries to the uterus. resulting in permanent sterility

**Uterine Artery Embolization:** Uterine artery embolization (UAE), which is referred to as Uterine Fibroid Embolization (UFE) by interventional radiologists, is a non-invasive, uterus-sparing treatment that involves killing fibroids by cutting off blood supply to the tumor

**Uterine Cornu (Cornua):** The two “horns” at the top of the uterus that contain the openings to the fallopian tubes.

**Uterine Fibroid:** Benign, or non-cancerous, tumors that grow on or within the uterine walls. These tumors vary greatly in size, ranging from an undetectable cell to the size of a large grapefruit. In some cases, fibroids can reach the size equivalent to that of a 5 to 6 month pregnancy. While uterine fibroids themselves are relatively painless and asymptomatic, their presence in the uterus can cause severe problems for a woman. Specifically, multiple small or few large fibroids can press against adjacent organs in the pelvic region, creating “bulk symptoms” such intense pelvic pain and pressure, low back pain, excessive uterine bleeding, elevated urinary frequency, anemia, constipation, hemorrhoids, and weight gain. Uterine fibroids are also referred to as myomas, myomatas, or leiomyomata.

**Uterine Perforation:** Penetration of a device through the uterine wall

**Uterus:** A small, hollow organ with thick muscular walls that supports the fetus during pregnancy

**Urethral insert:** A single-use device that is placed into the urethra to block the passage of urine. Indicated for women with stress incontinence, urethral inserts provide temporary protection against urine leakage resulting from exercise or other strenuous activities.

**Urge Incontinence:** A type of urinary incontinence that is characterized by frequent, sudden, and uncontrollable urges to urinate. Urge incontinence is typically caused by an overactive bladder (also called detrusor overactivity).

**Urinary Incontinence:** Involuntary leakage of the bladder

**Vaginal Hysterectomy:** Surgical removal of the uterus through an incision in the vagina

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**Ovion Exhibit 7**

1 of 1 DOCUMENT

**Staffbridge, Inc. et al. n1 v. Gary D. Nelson Associates, Inc. d/b/a Nelson Human Resources Solutions et al. n2**

n1 Scott Nieh, Laura Yao-Nieh and Nigel Lui.

n2 Gary D. Nelson.

**02-4912 BLS**

**SUPERIOR COURT OF MASSACHUSETTS, AT SUFFOLK**

*2004 Mass. Super. LEXIS 215*

**June 11, 2004, Decided**

**DISPOSITION:** [\*1] Order issued regarding pretrial motions.

**CASE SUMMARY:**

**PROCEDURAL POSTURE:** Plaintiff software developers sued defendants, a corporation and shareholder, for misappropriation of trade secrets, breach of contract, and breach of fiduciary duty by a shareholder in a closely held corporation. The developers moved to continue the pretrial conference and to modify the scheduling order so they could have more time for discovery. Defendants moved for reconsideration and allowance of their motion for summary judgment.

**OVERVIEW:** The developers claimed that defendants created workforce management software by misappropriating the trade secrets contained in the developers' software. Non-expert discovery was to have been completed almost a year earlier, and expert discovery was to have been completed over six months earlier. The court held that, in order for defendants to respond to the charges, and for the court to make appropriate findings and rulings, there had to be a clear designation that distinguished unique or proprietary material from the vast body of the developers' program and source code, so as to apprise a person what trade secrets in the developers' software they claimed was to be found in defendants' software. On the present record, not even a software expert could distinguish what it was in the developers' software that was actually protectable from that which was not. The developers were obliged to explain precisely what they claimed as trade secrets before they would be allowed any discovery of defendants' allegedly infringing materials.

**OUTCOME:** The developers were ordered to provide a second designation of what they claimed constituted the trade secrets allegedly misappropriated. If they did not, the court would grant defendants summary judgment on the first count, misappropriation of trade secrets. The adequacy of the second designation would dictate whether the case proceeded on all three counts or just on the latter two.

**LexisNexis(R) Headnotes**

*Constitutional Law > Procedural Due Process > Scope of Protection*

*Civil Procedure > Disclosure & Discovery*

[HN1] The judicial system is not a mere game of skill or chance in which the judge is merely an "umpire." A court will not permit the rules to subvert a just result. Due process requirements may affect the appropriateness of any response by a court for a request for additional time to complete discovery. To achieve justice, judges are expected to provide litigants with an opportunity for a trial when that is appropriate. A Massachusetts superior court is a tribunal of superior and general jurisdiction. Inherently it has wide power to do justice and to adopt procedure to that end.

**JUDGES:** Allan van Gestel, Justice of the Superior Court.

**OPINIONBY:** Allan Van Gestel

**OPINION:** *MEMORANDUM AND ORDER ON PLAINTIFFS' EMERGENCY MOTION TO CONTINUE*

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*THE PRETRIAL CONFERENCE AND RENEWED REQUEST FOR MODIFICATION OF SCHEDULING ORDER AND DEFENDANTS' CROSS MOTION*

This matter is before the Court literally on the eve of trial. There are two motions: an emergency motion by the plaintiffs seeking to continue the pretrial conference and a renewed request for a modification of the scheduling order governing this case; and an emergency cross motion by the defendants for fees and costs. The Court heard the parties orally on June 9, 2004.

#### BACKGROUND

The following procedural history provides some background.

The Tracking Order that issued on December 17, 2002, at the request and with the concurrence of the parties, called for all non-expert discovery to be completed almost a year ago, by July 30, 2003, and all expert discovery to be completed over six months ago, by December 1, 2003. In fact discovery was not only not completed in a timely fashion, it has barely begun.

The complaint presents three counts: misappropriation of trade secrets; breach of [\*2] contract for software licensing; and breach of fiduciary duty by a shareholder in a closely held corporation.

The plaintiffs are developers of workforce management software which they call StaffFind. The corporate defendant is a provider of temporary staffing. In May 2000, the parties entered into a license agreement under which the plaintiff would "do all work necessary to permit" the defendant to offer its customers a version of StaffFind that would manage certain information generated in the staff recruitment process. The plaintiff retained ownership in StaffFind, and the defendants agreed not to disassemble, de-compile or reverse engineer the software.

Allegedly because of dissatisfaction with StaffFind, the corporate defendant, with assistance from an independent company, created its own software product for the same purpose as StaffFind. The defendant's product is called WorkForceLogic ("WFL").

A prominent feature of the plaintiffs' claims is the charge that WFL was created by the misappropriation of the trade secrets contained in StaffFind.

In a December 1, 2003 letter from plaintiffs' counsel to defendants' counsel, the plaintiffs attempted to define or describe their trade [\*3] secrets. In response to what the plaintiffs proffered, the defendants responded with a detailed affidavit from Mark Crovella, an Associate Professor of Computer Science at Boston University, that asserted that the information presented by the plaintiffs

was insufficient to enable anyone to understand, identify and distinguish what trade secrets, if any, are in the StaffFind product. This Court examined the proffer and expressed its basic, albeit untrained, agreement with Professor Crovella. In part, the Court's reaction was sparked by its own recent experience in a remarkably similar case--*Softscape, Inc. v. Cambia Consulting, Inc.*, Suffolk Superior Court, No. 03-2824 BLS. n3

n3 In *Softscape*, a jury found for the plaintiffs on their claim that Cambria misappropriated its computer software trade secrets in violation of a licensing agreement. This Court, however, in ruling separately on a *G.L.c. 93A* count, found that no trade secrets were proved. *Softscape* is now believed to be on appeal, with the jury and the judge on opposite sides of the trade secret issue.

[\*4]

This Court noted in its earlier Order in this case:

Both for the defendants to respond to the charges against them, and for the Court to make appropriate findings and rulings on the case, there must be a clear designation that distinguishes unique or proprietary material from the vast body of the StaffFind program and source code, and appraises a person what trade secrets in StaffFind the plaintiffs claim are to be found in WFL. That cannot be done on the present record.

Recently, on June 2, 2004, this Court denied the defendants' motion for summary judgment and, treating the plaintiffs' earlier motion mentioned above as a Rule 56(f) motion seeking further discovery, denied it as well.

Once again, the same issues have arisen. The plaintiffs want more time for discovery and the defendants want reconsideration and allowance of their motion for summary judgment.

#### DISCUSSION

On the record before it--which has not effectively changed since last January--this Court should be disinclined to grant additional time for further discovery. See, e.g., *Greenleaf v. MBTA*, 22 Mass.App.Ct. 426, 429-30, 494 N.E.2d 402 (1986). At the same time, and admittedly arriving under a different circumstance, [\*5] this Court takes to heart Justice Dreben's admonition in *O'Connor v. City Manager of Medford*, 7 Mass.App.Ct. 615, 619, 389 N.E.2d 440 (1979):

[HN1] Our judicial system is not "a mere game of skill or chance" in which the judge is merely an "um-

pire." *In re Barnett*, 124 F.2d 1005, 1010-11. We will not permit the rules to subvert a just result . . .

Further, due process requirements may affect the appropriateness of any response by this Court to the present situation. See *Gos v. Brownstein*, 403 Mass. 252, 255-57, 526 N.E.2d 1267 (1988).

To achieve justice, judges are expected to provide litigants with an opportunity for a trial when that is appropriate. "The Superior Court is a tribunal of superior and general jurisdiction. Inherently it has wide power to do justice and to adopt procedure to that end." *Fanciullo v. B.G. & S. Theatre Corp.*, 297 Mass. 44, 51, 8 N.E.2d 174 (1937). For that reason, and one other, this Court will attempt here to craft an Order that is fair to both sides. The other reason is that this is not just a suit over the misappropriation of what are alleged to be trade secrets. Count II of the complaint seeks relief for breach of the licensing agreement, [\*6] a claim that does not necessarily require a trade-secret underpinning. Nor does Count III, which is against the individual defendant for breach of his fiduciary duties as a shareholder in a close corporation.

Before any discovery relating to trade secrets themselves is permitted, however, this Court must revisit the issue of the plaintiffs' designation of what it is that they claim are trade secrets. This effort has caused a careful re-reading of the Affidavit of Professor Crovella (Paper # 21) and the Affidavit of Michael Stonebraker (Paper # 30) submitted by the plaintiffs.

Attached to the Crovella Affidavit as Exhibit 2 is the December 1, 2003, letter from plaintiffs' counsel to defendants' counsel enclosing what is characterized as "the designation of trade secret material . . . with respect to StaffFind and its components." Enclosed with the letter are 11 pages of description, with three multi-page exhibits. Almost all of the foregoing is not understandable to a lay reader like the Court, not because it is unreadable, but because it is presented in un-understandable software jargon.

Professor Crovella's background and curriculum vitae demonstrate that he is immensely qualified [\*7] to speak with authority on the subject at hand. As noted above, he is an Associate Professor in the Department of Computer Science at Boston University. He holds a B.S. from Cornell University, an M.S. from the State University of New York at Buffalo, and an M.S. and a Ph.D. in Computer Science from the University of Rochester.

In his Affidavit, Professor Crovella explains and states that "it is impossible to identify what trade secrets, if any, are present in the StaffFind product" from a review of what was provided to him. He goes on to say that this "deficiency would prevent anyone comparing the

two programs [StaffFind and WFL] from vetting WFL for trade secrets supposedly found in StaffFind." This is because "the Designation includes functional characteristics that would be present in any similar software program; fails to separate claimed secrets from the vast body of source code designated; and fails to distinguish between data dictated by user-visible requirements and actual trade secrets."

At oral argument on the present motions, counsel for the plaintiffs stated that there were three matters that constituted his clients' trade secrets: the source code as a whole; the database [\*8] schema; and the customer databases.

Professor Crovella summarized his comments as to each of those three matters in the following ways.

1. The source code designation "fails to separate the claimed secrets from the vast body of source code designated; and without this, it is impossible to determine whether such claimed trade secrets are present in the WFL software, and whether those claimed trade secrets are in fact generally known to the trade";

2. The database schema designation "makes no distinction between the portions of the database tables, field definitions, and formats that would be naturally dictated by user-visible requirements, and those portions (if any) that represent trade secrets, the posited similarity would tell nothing"; and

3. The customer databases designation "does not distinguish unique or proprietary material from the vast body of the StaffFind program and source code (including its patently generic portions), and does not apprise a person what trade secrets StaffBridge claims are to be found in WFL."

Professor Michael Stonebraker, who submitted an affidavit on behalf of the plaintiffs, possesses a similarly impressive curriculum vitae. He is a retired [\*9] professor at both the University of California at Berkeley and at its Graduate School. He holds a B.S.E.E. from Princeton University and a Ph.D. in Computer Information and Control Engineering from the University of Michigan.

Professor Stonebraker, in his Affidavit mentions that he has reviewed Professor Crovella's Affidavit, however, Professor Stonebraker makes no effort in his own Affidavit to address the problems and concerns raised by Professor Crovella. Rather, in general and conclusory language, Professor Stonebraker opines that "StaffBridge is entitled to claim as a trade secret the data in the customer databases for Veritas, Brocade and Barclays Global Investors" and that "StaffBridge is also entitled to consider its database schema a trade secret, not because it is novel, in and of itself, but because access to the da-

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tabase schema would enable a software programmer to develop WorkForceLogic in such a way as to enable an expeditious conversion of StaffBridge customer databases to the WorkForceLogic platform."

Aside from conceding that he "finds the StaffBridge program not particularly novel," Professor Stonebraker otherwise engages mostly in speculation about how WFL was [\*10] created and that it must have been copied from StaffFind. Nothing in Professor Stonebraker's Affidavit would permit even a person with Professor Crovella's expertise, let alone a person with this Court's limited lack of expertise, to know and be able to distinguish what it is in the StaffFind software that is actually protectable from that which is not.

While perhaps rewarding the lackadaisical and the less than diligent pursuit of discovery, the interests of justice warrant giving the plaintiffs one final chance to pull up their socks and get ready for trial. But such an opportunity cannot be at the risk of the defendants' entitlement to know with precision what is claimed as a trade secret before any discovery of the defendants' allegedly infringing materials. See, e.g., *SmithKlineBeecham Pharmaceuticals Co v Merck & Co, Inc*, 766 A 2d 442, 447 (Del. 2000); *Computer Economics, Inc v. Gartner Group, Inc*, 50 F. Supp. 2d 980, 989 (S.D.Cal. 1999).

#### ORDER

1. On or before June 30, 2004, the plaintiffs, through their counsel, may have the opportunity to provide to the Court and the defendants, through their counsel, a second designation, in affidavit [\*11] form and under oath, that sets forth with rigorous and focused particularity what, and only what, the plaintiffs claim to constitute the trade secrets allegedly misappropriated by either of the defendants that form the basis for this law suit.

The designation must, with clarity that can be understood by a lay person, make clear and distinguish what is protectable from that which is not.

2. Upon receipt of the second designation referred to in paragraph 1 above, the defendants shall have until July 23, 2004, to submit to the Court and counsel for the plaintiffs, a response to the second designation.

If the response is other than an acceptance of the adequacy of the second designation, the defendants' response, like the plaintiffs' second designation, shall be in affidavit form and under oath.

3. The Court will hold a status conference on August 4, 2004, at 2:00 p.m., for the purpose of discussing the future course of this case.

A. If no second designation is served by the plaintiffs within the time provided, then this Court will grant summary judgment in favor of the defendants on Count I relating to the trade secret issues and will expect the parties to present proposals for possible [\*12] minimal further discovery and litigation, if any, on Count II for breach of the licensing agreement and Count III for breach of fiduciary duties by the individual defendant.

B. If a second designation is served and accepted for adequacy, without waiving any rights to challenge the trade secret nature of what is designated, then the Court will expect the parties to present proposals for further minimal discovery and litigation of the entire case.

C. If a second designation is served and not accepted for adequacy, then the Court, at the status conference, will accept such written filings either side chooses to make and will hear oral argument on the parties' respective positions. The Court's subsequent decision on the adequacy of the second designation will dictate whether the case proceeds on all three counts or just on Counts II and III.

Allan van Gestel

Justice of the Superior Court

DATED: June 11, 2004